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Issue 03-2 Autumn 2003/Winter 2004

The Reporter is published by the Massachusetts Department of Public Health, Division of Food and Drugs, Food Protection Program and the Division of Community Sanitation. For further information on these and other topics, Food Protection Program staff may be reached by calling 617-983-6712 and Division of Community Sanitation staff may be reached by calling 617-983-6762.

This publication is sent to all Boards of Health in the Commonwealth. It is requested that a copy be circulated to all board members and interested employees. Other interested individuals and agencies may request a copy by contacting the Editor.

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Letter from the Directors:

After 35 years of dedication and service to the Massachusetts Department of Public Health, Howard Wensley retired.

Howard joined the Division of Community Sanitation in 1978, and shortly thereafter became its Director. In this role, Howard became responsible for the prevention of avoidable death and morbidity through the enforcement of the State Sanitary Code, and was the *de facto* expert on the state's regulations pertaining to housing, swimming pools, bathing beaches, farm labor camps, recreational camps for children, correctional facilities, infectious waste, family-type campgrounds and nuisance-type conditions.

His expertise, interpretation, and enforcement of these regulations is known throughout the Commonwealth. His integrity and grit while fulfilling this role is also widely known and appreciated.

Fortunately for the citizens of Massachusetts, the Department of Public Health, and his colleagues, Howard has accepted a post-retirement role as a once per week consultant within the Department. Therefore, Howard's expertise and institutional knowledge are still available.

During Spring 2003, the FPP along with the other members of the Working Group for Foodborne Illness Control began a bi-monthly newsletter. The first three editions of the Newsletter are included in this edition of THE REPORTER. All editions of the newsletter are available at: http://www.state.ma.us/dph/fpp/retail/newsletter.htm

In our attempt to keep you informed about food bio-security issues, we are including some noteworthy articles in this edition of the REPORTER:

- Protecting the Food Supply - FDA Actions on New Bioterrorism Legislation, Fact Sheet on FDA'S New Food Bioterrorism Regulation: Interim Final Rule - Registration of Food Facilities
- USDA CONSUMER ALERT: Keeping Food Safe During An Emergency (in English and Spanish)
- Progress Report to Secretary Tommy G. Thompson: Ensuring the Safety and Security of the Nation's Food Supply

Two other timely articles are also included: Cruising with Confidence (by the FDA), and Surveillance Data from Swimming Pool Inspections - Selected States and Counties, United States, May--September 2002 (by the Centers for Disease Control and Prevention - CDC)

The FPP continues to strive to fulfill its mission of inspecting facilities, responding to consumer issues, and updating regulatory requirements. The budgetary constraints have been difficult, however all mandated requirements are being fulfilled, and staff continue to work with zeal and responsibility. In addition to fulfilling the day-to-day responsibilities of the FPP, additional accomplishments are noteworthy:

- In September 2003, an amended 105 CMR 561.000: *Frozen Desserts and Frozen Dessert Mixes* was promulgated by the Office of the Secretary of State.

- By the end of 2003, work completed on the CDC (U.S. Centers for Disease Control and Prevention) Epidemiology Laboratory Capacity grant will include the visiting of twenty of the largest local Boards of Health in order to assess and to improve the reporting of foodborne illnesses, both individual cases and outbreaks. And, since Spring 2003, three two-day classes focusing on the training of local health agents were conducted, and three more are planned through March 2003. Thus the FPP, in conjunction with the Massachusetts Health Officers Association, will have offered twelve of foodborne illness training sessions since May 2002.

- In September, a "Validation and Field Verification of HACCP and Risk Control Plans in Retail Food Establishments" 2-day training session was completed by 25 regulators and consultants. This is the fifth time the FPP has presented the class in the last 15 months.

- The FPP was awarded a F.D.A. Partnership Grant to conduct a forum for a broad-based discussion of food safety and security. These monies will be used to facilitate meetings of the "Massachusetts Food Safety and Security Coalition."

- In June 2003, a delegation of officials from the European Commission, Health and Consumer Protection Directorate-General's Office visited the United States to conduct an oversight and evaluation of the seafood industry and processing in the United States. The goal of this mission was to evaluate whether European Union (EU) countries should continue to accept U.S. exported seafood product - both raw and processed.

- Massachusetts was selected as one of the four inspectional sites that the EU members wished to audit. Sean Bowen, Senior Supervisory Inspector of the FPP's Seafood and Shellfish Unit was selected by the FDA District Director to conduct the 3-day inspection. The inspection and review were more than satisfactorily completed, and the mission report stated that the Massachusetts inspection was noted for its thoroughness, quality and detail, as well as the inspector's knowledge of the seafood inspectional process.

During Summer 2003, Everett Gasbarro and Tara Harris joined the FPP as Senior Food and Drug Inspectors. Both are presently assigned to the Food Processing Unit, but are being trained in all aspects of the inspectional responsibilities required for FPP staff. Prior to joining the FPP, Inspector Gasbarro was a sanitarian for the Town of Saugus Health Department, and Inspector Harris was a bacteriologist in the Clinical Investigations Laboratory at the State Laboratory Institute.

Foodborne Illness Information

from the Working Group on Foodborne Illness Control

March/April 2003 *Massachusetts Department of Public Health* **Vol 1, No. 1**

Monthly Statistics

Number of Complaints Received by the Working Group on Foodborne Illness Control (Confirmed and Unconfirmed)

Month	Single Reports (one person ill)		Multiple (two or more people ill)	
	2003	Average (1997-2002)	2003	Average (1997-2002)
January	21	17	14	12
February	17	18	10	13
March	10	21	6	14
April	19	20	4	11

Laboratory Confirmed Cases Reported to the Division of Epidemiology and Immunization.

Month	*Campylobacter* spp.		*Salmonella* spp.		Shiga-toxigenic *E. coli*	
	2003	Ave. (1997-2002)	2003	Ave. (1997-2002)	2003	Ave. (1997-2002)
January	74	70	54	67	2	5
February	54	65	43	65	0	4
March	58	82	60	76	0	5
April	59	89	52	89	2	7

What's New in Foodborne Illness: Outbreaks and New Information

Norovirus Outbreak, April 2002

On April 30, 2002, the Division of Epidemiology and Immunization (EPI) of the Massachusetts Department of Public Health (MDPH) was notified by the Boston Public Health Commission (BPHC) of a foodborne outbreak at a wedding held at a hotel in Boston on April 27, 2002. On May 1, the Division of Food and Drugs (DFD) of the MDPH received two additional reports of outbreaks at weddings in Framingham and West Bridgewater that occurred on April 27th. One evident commonality between the three outbreaks was that all locations served cakes prepared by a bakery located in Braintree, MA. The focus of the investigation quickly shifted from the locations where the weddings were held to the bakery.

The suspect bakery typically produces a large volume of product, and the weekend of April 26th and 27th was no exception. On that weekend, the bakery provided cakes for 46 weddings in addition to filling 800-900 orders for smaller cakes. EPI attempted to contact organizers from all of the weddings. Forty-two weddings were contacted and twenty-two reported some illness in guests and/or food employees who ate at the event.

In initial reports, guests and food workers reported experiencing symptoms of nausea, vomiting and diarrhea. Most cases experienced onsets approximately 24 hours after the event. There were few visits to medical providers, and no one was diagnosed with a bacterial enteric illness. Because of the prominence of vomiting, the 24-hour incubation period, the self-limiting nature of the disease, and a lack of the identification of a bacterial pathogen, a viral etiology was suspected.

The Braintree Health Department initiated an environmental investigation on May 1st. Employees were observed to change tasks without changing gloves and did not always wash hands between glove changes. The person in charge was observed touching a bare body part without washing his hands afterwards. The Braintree Health Department worked diligently with

this establishment to correct these hygiene issues.

Food employees at the bakery submitted stool samples for both bacterial and viral testing. Three food workers admitted being ill during the week prior to the wedding, but only one reported gastrointestinal symptoms. This employee admitted being ill on April 26th and working that day but did call in sick on the 27th. This employee was responsible for transferring cakes before and after decorating and shaving chocolate, however the wedding cakes did not contain any shaved chocolate. No food employees tested positive for bacterial pathogens, but the one who reported having gastrointestinal symptoms was positive for norovirus. In addition, two guests and a food employee from a different establishment also tested positive for the same strain of norovirus.

EPI distributed over 1500 surveys to guests and food employees. Nine hundred and thirty-seven surveys were returned for a response rate of 54%. Three hundred and thirty-four people were identified as cases for an attack rate of 36% among respondents. The most common symptoms reported were nausea (81%), diarrhea (79%), abdominal cramps (75%), and vomiting (60%). Onsets ranged from 6 hours to 3.5 days, but the average was 1.5 days. Nine percent visited a health care provider and 2% went to the hospital. The surveys were analyzed to determine which foods were statistically related to illness. In nine events, eating cake was associated with illness. An attempt was made to determine if a particular filling was associated with illness. Most of these cakes were multi-layered with several types of cake and fillings for the different layers. The strawberry Grand Marnier and the chocolate mousse filling were statistically associated with illness. Both of these fillings are made from the same base of white chocolate mousse filling. The preparation of the fillings was reviewed carefully, but no problems were identified. Several leftover cake samples were submitted to the Johns Hopkins School of Public Health for viral testing. No evidence of viral contamination was found, but the technique for doing viral detection in food is still under development.

There is strong epidemiolgical evidence that the cakes became contaminated by an infected food worker who used bare hands to prepare the cakes. Only one food worker tested positive, but it is impossible to be sure whether this worker alone caused the outbreak. According to all reports, this worker had minimal opportunity to contact the cakes with bare hands, but it is possible that this worker did more tasks than reported to the investigators. It is also possible that more workers were infected but had ceased shedding viral particles by the time their stool samples were collected. No one else reported gastrointestinal illness, but it is possible they were asymptomatic, experienced only mild symptoms, or were reluctant to disclose an illness to the investigators. Among other things, it was recommended that the establishment improve personal hygiene and develop an employee health policy.

Braintree Health Department Perspective: "Let's Investigate"

The Tale of a Foodborne Illness Outbreak Investigation

by Mary Beth McGrath, RS and Holly Sutherby, Braintree Health Department

On the evening of Tuesday April 30, 2002 a local permitted caterer reported a consumer notification of illness among 25 of 208 guests from a wedding catered by that establishment on Saturday April 27, 2002.

As the wedding was held at a function hall located in another town, we immediately made contact with the local Board of Health in that town to report the suspected foodborne illness outbreak. Subsequently, on the morning of May 1, 2002, an environmental investigation was conducted at the commissary of the local caterer. By midday, contact was made with the Massachusetts Department of Public Health Division of Food and Drugs (DFD) to report the suspected foodborne illness outbreak, and the investigation steps that the department had taken to this point. During this conversation with the DFD, they advised us that two other weddings from the same weekend reported illness among large numbers of guests. Upon further discussion with DFD, we determined that the common food item at all three weddings were the cakes provided by a local bakery in Braintree.

With this new source of information, the outbreak investigation went in another direction to focus on the local bakery. On the afternoon of May 1, 2002, an environmental investigation began at the local bakery. During this investigation all critical violations were corrected prior to the inspector's departure. As can happen, in addition to this environmental investigation, the department staff was involved in a hazardous materials incident which made it an extremely busy day at the Braintree Health Department.

As the days passed, further reports of illness were received by the DFD involving cakes from the local bakery. On May 8, 2002, the local bakery

voluntarily released a press/news alert to assist with the investigation, which continued at the bakery daily from May 1 through May 15, 2002 and subsequent dates thereafter. During this period, the department implemented control measures at the bakery, and provided supervision, training and consultation. The department deemed it prudent to act in the capacity as "consultant" to the establishment to ensure compliance with the control measures implemented. During the investigation, the owner of the establishment was unable to demonstrate the ability to ensure compliance with the State Sanitary Code, 105 CMR 590.000. Moreover, the owner, who was also the person-in-charge (PIC), demonstrated poor hygienic practices and unsafe food handling practices, thus setting a poor example for his employees. As such, the owner was removed from his supervisory capacity as the PIC, and another certified food handler within the bakery, who demonstrated food protection knowledge, was assigned to supervise the owner and the employees of the bakery.

At the conclusion of the investigation, it was determined that an employee of the bakery tested positive for norovirus. However, the mode of transmission by this individual to the cakes remains unknown.

It is quite amazing to see how the investigation evolved and took many different paths. One positive aspect of this outbreak investigation was the open communication and cooperation that was exhibited by all parties involved from the local food establishments to the enforcement agencies. Although, this situation was extremely challenging and time consuming, the communication and collaboration demonstrated did provide the ability for the local bakery to remain in operation and meet all compliance requirements, while ensuring there were no public health risks.

Food Safety Web Links: Highlights of the Month

Food Safety Information in Multiple Languages:

The Integrated Food Safety Information Delivery System:
http://www.profoodsafety.org/

The Integrated Food Safety Information Delivery System (IFSIDS) web site contains food safety fact sheets covering the day-to-day operation of a food establishment, such as proper hand washing techniques, use of a three-compartment sink, and hot and cold holding temperatures. The site also contains ready-to-use signs in English and thirteen foreign languages.

University of Massachusetts, Nutrition Education Program:
http://www.umass.edu/umext/nutrition/programs/food_safety/resources/index_new.htm

This site contains food safety information for consumers and food employees in multiple languages.

FBI Information on the Web:

Preliminary FoodNet Data on the Incidence of Foodborne Illnesses --- Selected Sites, United States, 2002:

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5215a4.htm

Foodborne Illness Information

from the Working Group on Foodborne Illness Control

May/June 2003 *Massachusetts Department of Public Health* **Vol. 1, No. 2**

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May	86	117	95	102	5	12
June	84	161	95	138	4	18

What's New in Foodborne Illness: Outbreaks and Information

Suspect *Clostridium perfringens* outbreak

On October 4, 2002, Boston Inspectional Services Department received an email from a consumer reporting that 6-7 people had become ill after sharing a meal with 20 people. The food had been prepared at a Boston restaurant and had been brought into their office for a meeting. Foods served included grape leaves, rice, chicken, lamb, kafta, falafel, hummus, babghanouj, taboulleh, salad, and baklava. One of the cases was contacted by phone and reported that the ill people experienced symptoms of diarrhea, nausea, abdominal cramps and fever that began 11-13 hours after the meal. The symptoms lasted 1 to 2 days and no one sought medical attention. According to the initial email complaint, only those who ate lamb became ill, while many who ate the kafta or chicken instead of the lamb did not become ill.

Left over food was available for testing and was brought into the Food Microbiology Laboratory at the State Laboratory Institute. Cooked grape leaves, roast lamb, red sauce, kafta and white sauce were analyzed. The Food Laboratory routinely performs coliform counts and standard plate counts and other tests as indicated. Due to the onset and nature of the symptoms in this outbreak, the food was also tested for *Clostridium perfringens*.

C. perfringens was cultured from the roast lamb at a level of 8,900,000 per gram. *C. perfringens* was

also cultured from the kafta but at a much lower level of 87,000 per gram. In addition, the red sauce had an estimated standard plate count of 2,600,000 per gram, and the white sauce had an estimated standard plate count of 57,000,000 per gram as well as a high total coliform count of 2,600 per gram with fecal coliforms <10 per gram. The very high level of *C. perfringens* in the lamb is at a pathogenic level. Small amounts of *C. perfringens* may be found in food without causing illness, but when found at a level above 10,000 per gram in an epidemiologically implicated food, it is strong evidence that the food caused the illness. In addition, the high standard plate counts in the two sauces may be an indication of poor food handling practices.

The environmental investigation revealed many significant violations especially concerning hot holding temperatures. Lamb on a steam table was found to be at 90°F. Rice was found at 110 °F, chicken at 110 °F and kafta patties were at 115 °F. Hot foods must be held at 140 °F or higher in order to prevent the proliferation of pathogens. In this outbreak, it is probable that the improper hot holding of the lamb allowed for the outgrowth of *C. perfringens* spores to pathogenic levels.

In this outbreak, the combination of the reported symptoms, the lab results and the environmental investigation makes it very likely that these patrons suffered from *C. perfringens* toxicoinfection from eating the lamb from this Boston establishment.

C. perfringens is a significant cause of foodborne illness in the United States and is estimated to result in 250,000 cases each year. It should be suspected as a cause of an outbreak based on the incubation period, type of symptoms and foods eaten. The most common symptoms are diarrhea with abdominal cramps. Fever and vomiting are rare. Symptoms typically begin 8-22 hours after ingestion of the offending food and usually last no more than 24 hours.

Clostridium perfringens is present in soil and also in the gastrointestinal tracts of healthy animals and humans. It is thought to be naturally present in many foods. The foods most commonly associated with outbreaks are cooked meats, gravy and casseroles. Since it is a spore-former, *C. perfringens* can survive high temperatures during initial cooking. The spores can then germinate during cooling of the food, and if the food is improperly held at temperatures between 60°F-125°F (16°C-52°C), the vegetative forms can multiply to high levels. If the food is then served without adequate reheating, these live vegetative forms may be ingested and can then produce the toxin that causes diarrhea and abdominal cramping. Therefore, the best way to prevent illness from this pathogen is proper cooling, proper hot and cold holding, and thorough reheating of foods.

For more information about *Clostridium perfringens* see http://www.cfsan.fda.gov/~mow/chap11.html

Foodborne Illness Investigation and Control Procedures:

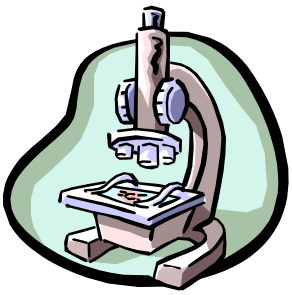
Collecting Stool Samples from Food Employees: Why, When and How

Testing food employees for enteric infection is a critical part of a thorough foodborne illness investigation. Infected food workers can be a cause of foodborne illness outbreaks. Testing not only helps determine the source of the outbreak, but it also helps to ensure that food employees are not currently infected and do not pose an ongoing threat to the public's health. Many food employees eat at the establishment at which they work and may become infected along with patrons. Failure to identify these workers and keep them from working could result in further outbreaks of foodborne illness. Needless to say, there is often significant initial resistance from both employers and employees when requested to submit stool samples; however, most will comply once they understand the importance of testing and the procedures for submitting the samples. Good preparation can make the process go more smoothly.

Stool samples are not collected from food employees in all outbreak investigations. The decision to test is based on the epidemiology of the outbreak and is decided on a case-by-case basis. The seriousness of the illness, number of people ill, population affected, symptoms and diagnosis are factors used to determine whether to test food employees. Testing should also be done when there is a strong suspicion that food employees were the source of infection or became infected during the outbreak. For example, if patrons became ill after eating at the same establishment but ate there on different days, then employees must be ruled-out as a source of the infection. Staff from the Division of Epidemiology and Immunization (EPI) and the Division of Food and Drugs (DFD) will help local health agents determine whether testing food employees is indicated.

The Diagnostic Laboratories at the State Laboratory Institute (SLI) can test for many bacterial pathogens and is in the process of validating a test for noroviruses as well. The laboratory routinely cultures for *Salmonella spp., Shigella spp., Campylobacter spp*., and *E. coli* O157:H7. They can also look for *Yersinia spp., Vibrio spp.* and Shiga-toxin if indicated. On occasion, the laboratory will also screen for *Bacillus cereus, Staphylococcus aureus* and *Clostridium perfringens*.

Norovirus testing will be done only when there is good epidemiological evidence that the foodborne outbreak is viral in nature. A viral cause is suspected if the onset of illness is between 12 and 48 hours, the duration of illness is 12 to 60 hours, vomiting is a common symptom and no bacterial cause has been identified. The decision to test for norovirus will be made by DFD and EPI in consultation with the laboratory.



Once the decision is made to test food employees, the process should begin as soon as possible to reduce the possibility of transmission of infection. In addition, food employees may be the only source for identifying an etiologic agent, and as time goes on, shedding of organisms in stool will decrease, and the chances of finding any positives will diminish.

The first step in the collection process is to educate management about the importance of testing so that they become a help and not a hindrance. It is difficult to collect stool efficiently without their cooperation, so it is important to explain to them why stool testing is needed and how it should be done. It is no surprise that most managers will resist asking their employees to submit stool samples. If, however, the time is taken to explain the reasons for the testing, most managers will do their best to ensure that their staff complies.

When talking with the management, it is very important to assure them that testing of food employees is standard procedure, that the purpose of testing is not to assign blame, and that they are not being singled out. It is simply one part of the investigation. It is also important to explain to them the importance of demonstrating that they currently have no infected food employees working so that the establishment can continue to operate safely. One outbreak in a lifetime is usually enough for any manager! It can also be pointed out that compliance with this request is a show of good faith that the establishment is working with the health department.

If, however, the management remains uncooperative, the request for stool samples should be put in writing. Use an Order for Correction letter that informs the employer that the health department has the authority to require the testing of food employees and can exclude them from work if they don't submit the required stool samples. Time is of the essence when testing food employees so don't delay in writing the letter and giving it to the manager. Contact DFD for a copy of a model Order for Correction letter if needed.

Collecting stool samples is relatively straightforward, however the procedures for bacterial testing differ from that for viral testing and have slightly different submission requirements. If both bacterial and viral testing is going to be done, both submission procedures must be explained very carefully to the employees since they will be required to submit two samples in slightly different ways.

For bacterial testing, there is a special collection kit that is specifically designed for enteric pathogen testing. The kits are available from SLI, and staff from DFD or EPI can assist in getting the kits to the local health department. The kits consist of a plastic tube containing a special transport medium and come with two outer metal containers for safe transport. The employee needs to produce a dime-sized sample of stool and place it in the transport medium. Once the sample is in the plastic container, it should be tightly shut. Any leakage of sample will invalidate the test and the employee will be required to resubmit.

Once the sample is placed in the transport medium, it should be kept at room temperature and NOT be refrigerated. Although it will keep at room temperature for 5 days, it should be sent to SLI as soon as possible.

Unlike bacterial testing, no transport medium is needed for norovirus testing. To test for norovirus, SLI needs 10-50 ml (at least 2 teaspoons) of a fresh stool sample in a sterile container. Containers are available from SLI, but sterile urine cups can also be used. The employees should be instructed to put their samples in the refrigerator as soon as they collect them. The samples should be kept cold until they reach SLI. Samples for viral testing should be submitted to the laboratory as soon as possible and preferably within 2 days of collection. Whether testing for bacteria or norovirus, make sure the employees know to submit stool and not urine! Every so often a urine sample is submitted by mistake.

Employees should be given 24 to 48 hours to submit stool samples. They are not expected to produce a sample on the spot! Employees who fail to submit stool specimens within that time period should be restricted from work until they comply. Many establishments, however, employ part-time workers or have workers with irregular schedules, and there is often an understandable delay in adhering to that time frame. Efforts should be made to notify these workers as soon as possible about this requirement. If after 48 hours, compliance is poor, don't hesitate to give the manager an Order for Correction letter if one has not already been provided.

Whether testing for bacteria or for norovirus, all samples must be properly labeled with the employee's first and last name and the establishment's name and town.

A sample submission form comes with the enteric kit and must be filled out and submitted with the sample. The same form can be used for both viral and bacterial testing, and if both samples are submitted at the same time, the form only needs to be filled out once. Failure to properly label a sample or to fill out the form will invalidate the sample, and the food employee will be required to resubmit.

In outbreak investigations in which food employees are being tested, samples should be collected from all employees who contact food, clean utensils, clean equipment, clean linens or single-service/single-use articles. This usually means the entire staff, including bartenders, wait staff, hosts and hostesses, dishwashers and managers. Everyone must be tested so that any pathogens present will not be allowed to persist among the staff.

In outbreak investigations in which the etiology is unknown or a viral etiology is suspected, food employees will be required to produce one stool sample that is negative for bacterial pathogens. If norovirus is strongly suspected, they may also be required to submit an additional sample for viral testing. If, however, bacterial illness has been confirmed or is strongly suspected, employees will be required to produce two consecutive stool samples that are negative for bacterial pathogens. It is best to let employees know this up front so that they will be prepared to give two samples. The two samples must be collected at least 24 hours apart, so it is recommended that employees be given one collection kit at a time to ensure that they aren't simply splitting a sample. They should receive a second collection kit only when they have returned the first sample.

Keeping track of all these tests can be quite a challenge. To make this job easier, it is very important to have an accurate list, including first and last names, of all the food employees who will be submitting samples. The enteric laboratory at SLI must get a copy of the list so that they can track the submissions too. However, the local health agent has the primary responsibility for making sure all the employees submit the required stool samples. To help keep track of the submissions, there is a Stool Sample Submission Tracking Form available on the web at http://www.state.ma.us/dph/fpp/retail/investigations.htm.

It is strongly recommended that one person, either from the establishment or from the health department, be responsible for ensuring that all employees submit stool samples. Often, the manager can be trusted to do this, but the health agent must verify that all employees have complied. The health agent is also responsible for getting the samples to the laboratory and can bring the samples to SLI, mail them in or arrange for them to be sent by courier. Even though the enteric kits come with individual mailers, it is not advisable to trust employees to mail their own, since this practice often results in an unusually high number of samples being "lost in the mail".

While the stool samples are being collected and tested, the food employees are usually allowed to keep working as long as they are not symptomatic. Employees with gastrointestinal symptoms must not be allowed to work until they produce the required negative stool samples. Occasionally, when there is a strong suspicion that the employees are the source of the outbreak, they will all need to be excluded, even if they have no symptoms, until they test negative. In most cases, this will result in the closing of the establishment.

Employees who test positive for a bacterial enteric pathogen should not be allowed to work, even if they have no symptoms. They can only return to work after producing two consecutive negative stool samples. If they have been treated with antibiotics, they cannot submit stool samples until 48 hours after they finish their medication. Sometimes employees prefer to do the follow-up testing with their private physicians. If they do, the health agent must see a copy of the laboratory reports showing the negative stool culture results before allowing the employee to return to work.

Employees who test positive for norovirus are allowed to return to work 72 hours after their symptoms stop. If they had no symptoms, they can return to work 72 hours after their sample was collected.

Testing food employees is a crucial part of a foodborne illness outbreak investigation. It is critical for determining the cause of the outbreak as well as ensuring that the workers in the establishment do not pose an ongoing threat to public health. While many people initially resist providing a sample, with persistence and patience it is possible to get 100% compliance.

Food Safety Web Links: Highlights of the Month

FBI Outbreak Report:

"Foodborne Transmission of Hepatitis A– Massachusetts, 2001"
MMWR, Vol. 52, No. 24, June 20, 2003, pp. 565-567, available on line at:
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5224a2.htm

This MMWR article summarizes an outbreak of Hepatitis A in Massachusetts which was ultimately traced to a local food establishment.

FBI Statistics:

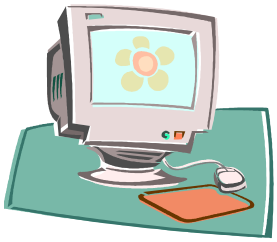
Mead, Paul, et al. "Food-Related Illness and Death in the United States," Emerging Infectious Diseases, Vol. 5, No. 5, September-October, 1999
available on line at:
http://www.cdc.gov/ncidod/eid/vol5no5/mead.htm

This article provides the most comprehensive estimate of the burden of foodborne illness in the United States. The Emerging Infectious Diseases journal is published by CDC and provides cutting edge information about emerging infectious diseases including many foodborne diseases.

Food Safety:

Gateway to Government Food Safety Information: www.foodsafety.gov

This website is a portal to food safety information from federal and local governments. It includes information from USDA, FDA, EPA, CDC as well as links to state health departments. Much of the information is appropriate for regulators and consumers alike.



Foodborne Illness Information

from the Working Group on Foodborne Illness Control

July/August 2003 *Massachusetts Department of Public Health* **Vol. 1, No. 3**

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July	8	19	12	11
August	28	28	16	13

Laboratory Confirmed Cases Reported to the Division of Epidemiology and Immunization.

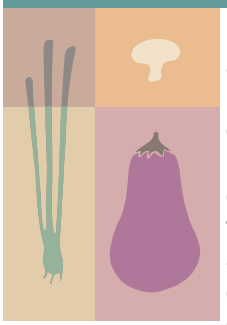
Month	*Campylobacter*		*Salmonella*		Shiga-toxigenic *E. coli*	
	2003	Ave. (1997-2002)	2003	Ave. (1997-2002)	2003	Ave. (1997-2002)
January	74	70	54	67	2	5
February	54	65	43	65	0	4
March	58	82	60	76	0	5
April	59	89	52	89	2	7
May	86	117	95	102	5	12
June	84	161	95	138	4	18
July	34	156	146	158	5	28
August	29	127	120	175	3	24

What's New in Foodborne Illness: Outbreaks and Information

Outbreak of *Salmonella* Hadar Linked to a Single Establishment in Southeastern Massachusetts: October 2002

Foodborne illness outbreaks are typically recognized when several people get ill soon after sharing a meal at an event such as a church picnic, wedding or other party. Public health officials usually learn about these outbreaks when one of the patrons realizes several in their party are ill and calls the health department. This is an effective method for detecting outbreaks when the common meal is obvious. However, not all outbreaks are detected in this fashion. Increasingly, outbreaks are first being discovered based on laboratory results.

In Massachusetts, when clinical laboratories confirm the diagnosis of certain infectious agents, they are required to report their results to the Massachusetts Department of Public Health (MDPH). For some pathogens, such as *Salmonella* species, the clinical laboratories also send the actual pathogen that they isolated to the Enteric Laboratory at the State Laboratory Institute (SLI) for further characterization. Staff from the Division of



Epidemiology and Immunization (EPI) and the laboratories review all the data in order to see if any diseases are occurring in unusual numbers or locations. If such a cluster of disease is detected, EPI will begin an investigation to try to determine if the cluster is in fact an outbreak that can be traced to a common exposure. MDPH investigated one such outbreak in southeastern Massachusetts in October of 2002.

On September 13, 2002, EPI was notified by the Enteric Laboratory at SLI of a cluster of three confirmed cases of *Salmonella* Hadar in residents of towns in southeastern Massachusetts. Since only one or two cases of *Salmonella* Hadar are typically reported each month, three cases could indicate an outbreak. EPI began an investigation to look for common exposures among the cases. When one of the cases was identified as a bartender at a local restaurant, the local health department in the town where the restaurant was located excluded the bartender from work until he submitted the required negative stool sample.

Over the next two weeks, the Enteric Laboratory received nine additional isolates of *S.* Hadar from residents of southeastern Massachusetts. EPI worked with local health departments to interview the cases to determine symptoms, onset dates, food histories and other potentially significant exposures. By September 27th, it was clear that many of the cases had eaten at that same restaurant where the positive bartender had worked. The cases reported eating different foods on various days since August 24th . They reported that symptoms began from 1 to 6 days after eating there. The predominant symptoms were diarrhea, abdominal cramps and fever. Nausea, vomiting, headache muscle aches and fatigue occurred to a lesser extent. Several people were hospitalized.

On September 27th, the Division of Food and Drugs contacted the local health department in the town where the suspect establishment was located. Because of the wide ranges of exposure and onset dates and the presence of a bartender who tested positive, it was strongly suspected that food workers were the source of the sporadic illnesses among patrons. In order to prevent further illness among patrons, all of the employees were excluded from work until they produced at least one negative stool sample, and submitted a second for testing. This effectively closed the restaurant on September 28th since the management was unable to get enough replacement workers to operate the establishment.

The local board of health oversaw the closing of the establishment and the collection and submission of stool samples from the employees. In addition, the manager was told to discard all open ready-to-eat foods and to thoroughly clean and sanitize all food contact surfaces. The management of the establishment was cooperative and agreed to comply with the requirements of the local health department and MDPH.

On October 2nd , the local health department conducted an inspection of the establishment while it was still closed. The inspector verified that the establishment was in good sanitary condition and that ready-to-eat foods had been discarded. The management had hired a professional cleaning service and had all the refrigerators and freezers checked to make sure they were functioning properly. However, in discussions with the management and some of the employees, it became evident that they were unaware of the importance of not working when ill with gastrointestinal symptoms. The manager was also unaware of his duty to ensure that the employees know to report specific symptoms and diseases to the person-in-charge.

Sixty-six full and part time employees were tested for bacterial enteric pathogens. Three food employees, in addition to the bartender, were positive for *S.* Hadar. A fifth was positive for *Salmonella* Adelaide. All of these employees, except the bartender, denied having symptoms of gastrointestinal illness in the recent past. None were allowed to return to work until they submitted two negative stool samples.

By October 3rd, enough food employees had tested negative to allow the establishment to re-open. The collection of second stool samples continued.

Approximately one month later, however, MDPH received reports of five additional cases of *S.* Hadar in patrons of this establishment. These cases had eaten at the restaurant on various days between October 4th and 31st. Again, because of the multiple dates of exposure, it was strongly suspected that one or more food employees were still shedding *Salmonella* and contaminating the food. The establishment again voluntarily

closed, and the employees were asked to submit additional stool samples.

This time around, two additional employees tested positive for *S.* Hadar, and another who had tested positive for *S.* Hadar the first time was now positive for *S.* Adelaide.

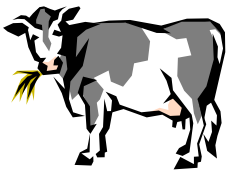
Initially, the management of this establishment decided to close for a month, but eventually they decided to close permanently. This closing made it exceedingly difficult to collect the rest of the stool samples. Forty-four employees did submit at least one stool sample. A letter and an enteric kit were mailed directly to the employees that hadn't submitted the required stool samples, but only two returned samples. Letters were also sent to local health departments in the towns in which these employees lived. The letters requested that the health agent contact the employees to ascertain whether they were still working in food service. If they were working in food service, they would be required to submit stool samples. Employees either could not be reached or reported no longer working in food service. There was no further attempt to obtain stool samples.

The *Salmonella* Hadar isolates from the patrons and the food employees were further characterized using pulsed-field gel electrophoresis (PFGE), commonly known as DNA fingerprinting. All of the isolates had PFGE patterns that were indistinguishable, which meant that a common source was likely and that the illnesses in the patrons were probably connected to the infected employees.

No common single food item was identified among the patrons who became ill, which supports the theory that infected food employees contaminated food served to the patrons over a prolonged period of time. Infected food workers can contaminate food if they fail to wash their hands thoroughly after using the bathroom and then prepare food without using gloves or utensils. Since *Salmonella* is killed by standard cooking temperatures, ready-to-eat foods are the most likely vehicles for this type of transmission, although contaminated food that is improperly cooked could also be a vehicle in this type of outbreak.

It is not clear how the food employees became infected with *Salmonella.* It is possible that these workers became infected after consuming a common contaminated meal at work, or it may have started with an infection in one employee that spread to others through person-to-person contact and/or by preparing food for each other.

As in this outbreak, it is not always obvious when food workers are infected with pathogens. There was no obvious illness or excessive absenteeism among the workers at this establishment. Therefore, it is very important that employees understand the importance of reporting symptoms of gastrointestinal illness to the person-in-charge. The person-in-charge and the manager must understand the importance of preventing ill employees from working and should make it possible for employees to report illness without fear of negative consequences. Finally, the person-in-charge should continually encourage the staff to practice good personal hygiene and to avoid bare-hand contact with ready-to-eat foods.



A Review: Shiga Toxin-producing *E. coli*

Shiga toxin-producing *E. coli* (STEC) have emerged as a significant problem across the United States, including Massachusetts. According to the Centers for Disease Control and Prevention (CDC), one STEC, *E. coli* O157:H7, causes an estimated 73,000 illnesses annually.

The incubation period for illness due to *E. coli* O157:H7 ranges from 2-8 days, with an average of 3-4 days. Symptoms include abdominal cramps, diarrhea, bloody diarrhea, nausea and vomiting, but infected individuals can also be asymptomatic. The infectious dose is low (<100 organisms), facilitating person-to-person transmission. Cattle and deer have been identified as reservoirs.

Ground beef is often implicated in *E. coli* O157:H7 outbreaks. In addition, other food items that have been identified as vehicles include deer meat, unpasteurized milk, unpasteurized apple cider and juice, alfalfa sprouts, radish sprouts, lettuce, potatoes and cantaloupe. Waterborne outbreaks of *E. coli* O157:H7 have also occurred as the result of drinking or swimming in contaminated, unchlorinated water.

Between 1997 and 2002, an average of 138 cases of *E. coli* O157 were reported in Massachusetts annually (Figure 1). The majority of the cases were among children under 20 years of age (Figure 2). As expected, there was a consistent increase in cases

during the spring and summer months.

Non-O157 STEC are also important pathogens, and are identified as the cause of outbreaks each year in the United States. The State Laboratory Institute (SLI) has identified an increase in non-O157 isolates over the last few years. This is most likely due to an increase in the availability of testing and typing of isolates. As of February 14, 2003, evidence of infection due to Shiga toxin-producing organisms is reportable by clinical laboratories (105 CMR 300.170) to the Massachusetts Department of Public Health (MDPH).

About 10 to 15 percent of children infected with *E. coli* O157:H7 develop hemolytic uremic syndrome (HUS), a serious condition which can be fatal.[1] HUS is characterized by the sudden rapid destruction of red blood cells, causing acute renal failure due partly to the impairment of small arteries in the kidneys. During the 5th year of national HUS reporting to the CDC, the median age of patients diagnosed with HUS was 4 years.[2] In 2000, MDPH established an active surveillance system to improve reporting of HUS. Active surveillance is the collection of disease-related information that places the burden of information collection on the investigator, in this case, MDPH. MDPH epidemiologists now contact Massachusetts-based pediatric nephrologists every two weeks and inquire about HUS cases newly identified. In 2002, there were 16 confirmed cases of HUS reported to MDPH (Figure 3). The median age of patients in Massachusetts diagnosed with HUS was 5 years, and the age range was 1 to 73 years. All the cases survived.

While most *E. coli* O157:H7 cases in Massachusetts are sporadic, there have been two significant *E. coli* O157:H7 outbreaks in the past 12 years. In Fall 1991, 23 cases of *E. coli* O157:H7 were identified in southeastern Massachusetts. Four of these cases were diagnosed with HUS. A case-control study implicated fresh-pressed, unpreserved apple cider as the vehicle. At the implicated cider mill, a large percentage of apples used to make the cider were "drops" (apples collected from the ground). The apples were not washed and brushed prior to processing. In addition, the cider-press operator raised cattle on his property.

In the summer of 1995, nine confirmed primary cases of *E. coli* O157:H7 were identified among patrons of a Mexican food concession stand at the Barnstable County Fair. A case-control study implicated beef-containing Mexican food from the concession stand. A hazard analysis critical control point (HACCP)

Figure 1. O157 STEC Cases, Massachusetts 1997-2002

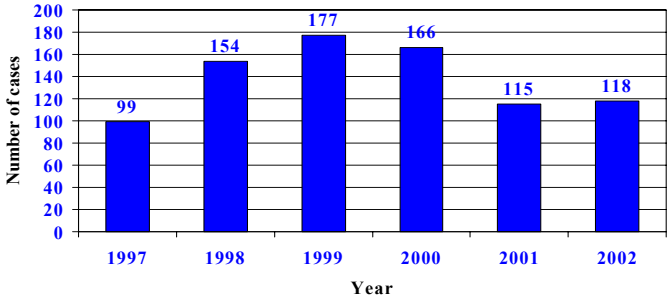


Figure 2. O157 STEC Cases by Age Group, Massachusetts 1997-2002

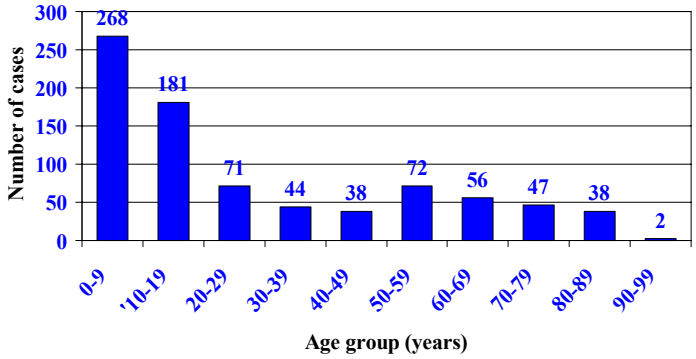
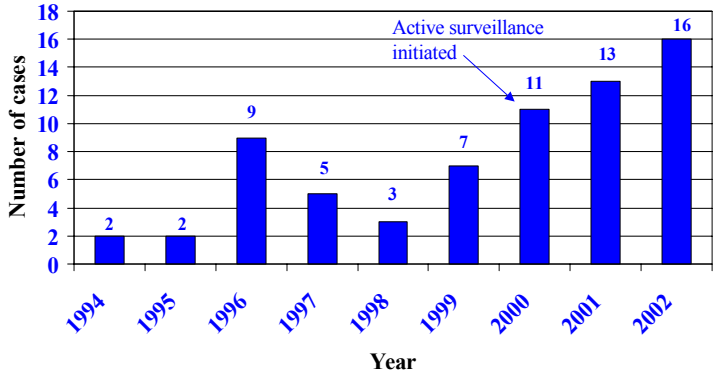


Figure 3. Confirmed HUS Cases Reported in Massachusetts, 1994-2002*



*Includes 25 cases from retrospective case review at Children's Hospital

evaluation of taco preparation at the concession stand revealed several high risk factors, including the partial cooking of large batches of ground beef and subsequent reheating of the beef without temperature monitoring. Partially cooked ground beef was also cooled improperly in a non-commercial refrigerator and refrigerated next to raw ground beef.

[1]Sawyer L. Prevention of hemolytic uremic syndrome (HUS) caused by infection with shiga toxin-producing Escherichia coli (STEC) with monoclonal antibody therapy, NIAID Presentation, Bethesda, MD, June 19, 2002.
[2]Centers for Disease Control and Prevention. Hemolytic uremic syndrome, postdiarrheal, MMWR 2002; 49: xiii.

Food Safety Web Links: Highlights of the Month

US Department of Agriculture: Food Safety Inspection Service
http://www.fsis.usda.gov/index.htm
This site contains everything you ever wanted to know about meat and poultry products. It also has a wealth of information about HACCP, including some sample plans. The site also has good information on food safety for the general public.

Safety Alerts
http://www.safetyalerts.com
If you are wondering whether a product has been recalled, this is the site for you. It contains information on all product recalls including food. It is up to date and easy to use.

Microbiological Standards and Guidelines
http://peaches.nal.usda.gov/foodborne/fbindex/Micro_Guidelines.asp
This site contains links to documents and websites from around the world that provide information on microbiological standards and guidelines for various foods.

And just for fun…….

http://foodsafe.ucdavis.edu/music.html
Go to this site to listen to fun food safety music. Professor Carl Winters from UC Davis has parodied popular songs making them into funny songs about food safety.

Protecting the Food Supply
FDA Actions on New Bioterrorism Legislation
Fact Sheet on FDA'S New Food Bioterrorism Regulation:
Interim Final Rule - Registration of Food Facilities

October 2003

US FDA, Health and Human Services
Center for Food and Safety and Applied Nutrition
http://www.cfsan.fda.gov/~dms/fsbtac12.html

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) directs the Secretary of Health and Human Services to take steps to protect the public from a threatened or actual terrorist attack on the U.S. food supply. To carry out the provisions of the Bioterrorism Act, FDA published, on October 10, 2003, an interim final regulation, *Registration Of Food Facilities*, which requires domestic and foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States to register with the FDA. Under this interim final regulation, all affected facilities must register by ***December 12, 2003***. In the event of a potential or actual bioterrorism incident or an outbreak of food-borne illness, facility registration information will help FDA to determine the location and source of the event and permit the agency to notify quickly facilities that may be affected.

Facilities can register online via the Internet, by completing a paper form, or submitting to FDA a CD-ROM with relevant registration information. The online registration system will be available for use on *October 16, 2003*. For assistance with online registration: in the U.S call 1-800-216-7331 or 301-575-0156; from elsewhere call 301-575-0156; or send a fax to 301-210-0247. Requests for assistance also may be emailed to furls@fda.gov. Beginning October 16, 2003, the Online Registration Help Desk will be staffed on business days from 7 AM until 11 PM U.S. Eastern Time.

This new regulation pertains *only* to facilities that manufacture/process, pack, or hold food, as defined in the regulation, for consumption in the U.S. Examples of "food" include:

- Dietary supplements and dietary ingredients
- Infant formula
- Beverages (including alcoholic beverages and bottled water)
- Fruits and vegetables
- Fish and seafood
- Dairy products and shell eggs
- Raw agricultural commodities for use as food or components of food
- Canned and frozen foods
- Bakery goods, snack food, and candy (including chewing gum)
- Live food animals
- Animal feeds and pet food

Food contact substances and pesticides are not "food" for purposes of the interim final rule. Thus, a facility that manufactures/processes, packs, or holds a food contact substance or a pesticide is not required to register with FDA.

Who must register? The owner, operator, or agent in charge of a domestic or foreign facility that

manufactures/processes, packs, or holds food for human or animal consumption in the U.S., or an individual authorized by one of them, must register that facility with FDA by **December 12, 2003**. A domestic facility must register whether or not food from the facility enters interstate commerce. A foreign facility must designate a **U.S. agent** (for example a facility's importer or broker), who must live or maintain a place of business in the U.S. and be physically present in the U.S., for purposes of registration.

What types of facilities do not have to register?

- ***Private residences of individuals***, even though food may be manufactured/processed, packed, or held there.
- ***Non-bottled water drinking water collection and distribution establishments and structures***, such as municipal water systems.
- ***Transport vehicles that hold food only in the usual course of their business as carriers***.
- ***Farms***, i.e., facilities in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. Washing, trimming of outer leaves, and cooling of produce are considered part of harvesting. The term "farm" also includes facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership, and facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership. A farm-operated roadside stand that sells food directly to consumers as its primary function would be exempt from registration as a retail food establishment.
- ***Restaurants***, i.e., facilities that prepare and sell food directly to consumers for immediate consumption, including pet shelters, kennels, and veterinary facilities that provide food directly to animals. Facilities that provide food to interstate conveyances, such as commercial aircraft, or central kitchens that do not prepare and serve food directly to consumers are not restaurants for purposes of the rule.
- ***Retail food establishments***, such as groceries, delis, and roadside stands, that sell food directly to consumers as their *primary function*, meaning that annual sales directly to consumers are of greater dollar value than annual sales to other buyers. An establishment that manufactures/processes, packs, or holds food and whose primary function is to sell food directly to consumers, including food that the establishment manufactures/processes, from that establishment is a retail food establishment and is not required to register.
- ***Nonprofit food establishments***, which are charitable entities that meet the terms of § 501(c) (3) of the Internal Revenue Code and that prepare or serve food directly to the consumer or otherwise provide food or meals for consumption by humans or animals in the U.S. Central food banks, soup kitchens, and nonprofit food delivery services are examples of nonprofit food establishments.
- ***Fishing vessels*** that harvest and transport fish. Such vessels may engage in practices such as heading, eviscerating, or freezing fish solely to prepare the fish for holding on board the vessel and remain exempt.
- ***Facilities regulated exclusively and throughout the entire facility by the U.S. Department of Agriculture***, that is, facilities handling only meat, poultry or egg products.

Do all foreign facilities that manufacture/process, pack, or hold food for consumption in the U.S have to register? No. If a foreign facility that manufactures/ processes, packs, or holds food sends it to another *foreign* facility for further manufacturing/processing or packaging before the food is exported to the U.S., only the *second* foreign facility is required to register. **However**, if the second foreign facility performs only a *de minimis* activity, such as putting on a label, *both* facilities would be required to register. Also, any foreign facility that *packs or holds* food after

the last foreign manufacturer/processor of the food must register.

How often must you register? Registration is required only once for each food facility. However, required registration information must be updated if it changes.

What does the registration number mean? It means that the owner of the facility has complied with this rule by registering with FDA. Assignment of the number does not convey FDA approval or endorsement of the facility or its products.

Is there a fee for registration? There is no fee for registration or for updates of any registration.

How can a facility register? Registrants must use Form 3537 to register or update a registration. Facilities may register online via the Internet at www.fda.gov/furls, which will operate 24 hours a day, seven days a week, beginning October 16, 2003. This web site is available from wherever the Internet is accessible, including libraries, copy centers, schools, and Internet cafes. In addition to the online help registrants can access at www.fda.gov/furls, there is also an Online Registration Help Desk:

- In the U.S call 1-800-216-7331 or 301-575-0156
- From elsewhere call 301-575-0156
- Fax questions to 301-210-0247
- Email questions to furls@fda.gov

Beginning October 16, 2003, these phone numbers will be staffed on business days from 7 AM until 11 PM U.S. Eastern Time.

If a facility does not have reasonable access to the Internet, a paper copy of the form may be obtained from FDA by calling 800-216-7331 or 301-575-0156 or by mailing a request to:
U.S. Food and Drug Administration
HFS-681
5600 Fishers Lane
Rockville MD 20857 USA

When the form has been filled out completely and legibly, it should be mailed to the above address or faxed to (301) 210-0247. Also, as noted immediately below, registrations for multiple facilities may be submitted to FDA on a CD-ROM.

Is there a mechanism for registering multiple food facilities at one time? FDA will accept multiple registrations submitted in CD-ROM format ISO 9660 (CD-R or CD-RW) data format. These files must be submitted on a Portable Document Format (PDF) of Form 3537 and be accompanied by one signed copy of the certification statement that appears on the registration form. Each submission on the CD-ROM must use the same preferred mailing address in the appropriate block on Form 3537. There is no maximum number of registrations that may be submitted in this manner. However, each registration on a CD-ROM must have a unique file name up to 32 characters long, the first part of which may be used to identify the parent company. If the information does not conform to these specifications, FDA will not process the registration(s) and will return the CD-ROM for correction.

FDA will process CD-ROM submissions along with mailed and faxed submissions in the order received.

Why does FDA encourage electronic registration? FDA encourages this mode of registration as the least costly and most efficient means for the facility as well as FDA. With electronic registration, all required information must be entered before the system will accept the submission. At that point, registrants will receive immediate confirmation of registration and a registration number. Paper registration will be a more costly and less efficient process to supply both FDA with the necessary facility information and facilities with their registration numbers. Further, paper registration may have a higher number of errors or omissions on the form, requiring additional time to complete the registration process.

What information is required? Each registration must include the name, address, and phone number for the facility and its parent company (if applicable); the name, address, and phone number of the owner, operator, or agent in charge; all trade names the facility uses; applicable food product categories as identified in FDA's regulation, 21 CFR 170.3; a statement certifying that the information submitted is true and accurate and that the person submitting the registration, if not the owner, operator, or agent in charge, is authorized to submit the registration. A foreign facility must also provide the name, address, and phone number of its U.S. agent. The foreign facility must also provide the emergency contact phone number for its U.S. agent unless the facility designates another person to serve as the emergency contact. A domestic facility must also provide an emergency contact phone number.

Is additional information requested? FDA is asking for, but not requiring, certain *optional* information on the registration form. The optional information will help us communicate more effectively with facilities that may be the target of an actual or potential terrorist threat or other food-related emergency. For example, some food products are not identified in the list of food categories at 21 CFR 170.3, such as certain dietary supplements, infant formula, and animal feed, but foods in these categories may be the focus of a food-related emergency. Therefore, FDA encourages, but does not require, submission of the information identified as optional on Form 3537.

Is registration information available to the public? No. Neither the list of registered facilities, any registration documents submitted under this regulation, nor any information derived from the list or the documents that would reveal the identity or location of a specific registered person is subject to disclosure under the Freedom of Information Act (FOIA).

What if the submitted registration information changes? When a required element of a facility's registration information changes, e.g., change of operator, agent in charge, or U.S. agent, the owner, operator, or agent in charge, or an individual authorized by one of them, must submit an update to the facility's registration within 60 days of the change through the Internet at www.fda.gov/furls or through the paper update process.

What if a facility goes out of business? When a facility goes out of business, its registration must be canceled using Form 3537a, either through the Internet, at www.fda.gov/furls, or through the paper process.

What if a new owner acquires an already-registered facility? The former owner must cancel the facility's registration within 60 days of the change (using Form 3537a), and the new owner must re-register the facility using Form 3537. Both cancellation and re-registration may be completed through the Internet or through the paper process.

What happens if a facility does not register? Failure of a domestic or foreign facility to register,

update required elements, or cancel its registration in accordance with this regulation is a prohibited act under the Federal Food, Drug, and Cosmetic Act. The Federal government can bring a civil action to ask a Federal court to enjoin persons who commit a prohibited act, or it can bring a criminal action in Federal court to prosecute persons who are responsible for the commission of a prohibited act. If a foreign facility is required to register but fails to do so, food from that foreign facility that is offered for import into the U.S. is subject to being held within the port of entry for the article unless otherwise directed by FDA or the Bureau of Customs and Border Protection (CBP). FDA plans to issue enforcement guidance regarding the agency's policies regarding refusals of imported food under section 801(m)(1) or holds of imported food under section 801(l). This guidance document will be available to the public, and FDA will publish a notice of its availability in the Federal Register.

Will additional comments be accepted on this interim final regulation? FDA is providing a 75-day comment period on specific issues related to this interim final rule. In addition, to ensure that those commenting on this interim final rule have had the benefit of FDA's outreach and educational efforts and have had experience with the systems, timeframes, and data elements of this interim final rule, the agency intends to reopen the comment period for an additional 30 days beginning in March 2004. Regularly updated information on this interim final rule and how to comment on it can be accessed electronically at http://www.fda.gov/oc/bioterrorism/bioact.html.

How will FDA enforce this interim final rule during the comment period? FDA will actively consider the exercise of its discretion in the enforcement of the Registration interim final rule while at the same time ensuring public health protection, both during initial implementation of the rule and thereafter. The Registration interim final rule takes effect on December 12, 2003 and covered entities are responsible for complying with the requirements in the rule at that time. FDA recognizes that a number of affected parties still may need assistance in understanding the rule's requirements and how to comply even after the extensive outreach and educational activities that FDA will be conducting before December 12th. Accordingly, for this and other reasons, FDA intends to put into place, during the initial months following the effective date, a policy that emphasizes assisting covered entities in understanding the requirements and how to comply. FDA will shortly publish a notice of availability for a Compliance Policy Guide that will outline how FDA generally intends to exercise its enforcement discretion. This guidance, however, will not affect FDA's ability to take actions that may be necessary, including conducting inspections for food safety and security concerns or taking any other action under the Federal Food, Drug, and Cosmetic Act. This policy will also not affect the ability of the Bureau of Customs and Border Protection to assess penalties under 19 U.S.C. 1595a(b) or to take enforcement action under any other authority.

For further information: For more details and information on the specific requirements of this interim final rule, please refer to the interim final rule itself. The interim final rule is available at http://www.cfsan.fda.gov/

USDA CONSUMER ALERT
Keeping Food Safe During An Emergency

Food Safety and Inspection Service
United States Department of Agriculture
Washington, D.C. 20250-3700

http://www.fsis.usda.gov/OA/news/2003/weatheradv.htm
Accessed: September 24,2003

WASHINGTON, Sept. 17, 2003 – The U.S. Department of Agriculture is providing recommendations in advance of the upcoming hurricane in an effort to help minimize the potential for foodborne illness.

Steps to follow to prepare for a possible weather emergency:

- Keep an appliance thermometer in the refrigerator and freezer. An appliance thermometer will indicate the temperature in the refrigerator and freezer in case of a power outage and help determine the safety of the food.
- Make sure the freezer is at or below 0˚F and the refrigerator is at or below 40˚F.
- Freeze containers of water for ice to help keep food cold in the freezer, refrigerator or coolers after the power is out.
- Freeze refrigerated items such as leftovers, milk and fresh meat and poultry that you may not need immediately - this helps keep them at a safe temperature longer.
- Plan ahead and know where dry ice and block ice can be purchased.
- Store food on shelves that will be safely out of the way of contaminated water in case of flooding.
- Have coolers on hand to keep refrigerator food cold if the power will be out for more than four hours. Purchase or make ice cubes and store in the freezer for use in the refrigerator or in a cooler. Freeze gel packs ahead of time for use in coolers.
- Group food together in the freezer – this helps the food stay cold longer.

Steps to follow after the weather emergency:

- Keep the refrigerator and freezer doors closed as much as possible to maintain the cold temperature.
- The refrigerator will keep food safely cold for about 4 hours if it is unopened. A full freezer will hold the temperature for approximately 48 hours (24 hours if it is half full and the door remains closed.)
- Food may be safely refrozen if it still contains ice crystals or is at 40˚F or below.
- Never taste a food to determine its safety!
- Obtain dry or block ice to keep your refrigerator and freezer as cold as possible if the power is going to be out for a prolonged period of time. Fifty pounds of dry ice should hold an 18-cubic-foot full freezer for 2 days.
- If the power has been out for several days, check the temperature of the freezer with an appliance thermometer or food thermometer. If the food still contains ice crystals or is at 40˚ F or below, the food is safe.
- If a thermometer has not been kept in the freezer, check each package of food to determine its safety. If the food still contains ice crystals, the food is safe.
- Discard refrigerated perishable food such as meat, poultry, fish, soft cheeses, milk, eggs, leftovers and deli items after 4 hours without power.
- Drink only bottled water if flooding has occurred.

- Discard all food that came in contact with flood waters including canned goods. Discard wooden cutting boards, plastic utensils, baby bottle nipples and pacifiers.
- Thoroughly wash all metal pans, ceramic dishes and utensils that came in contact with flood water with hot soapy water and sanitize by boiling them in clean water or by immersing them for 15 minutes in a solution of 1 teaspoon of chlorine bleach per quart of water.

When in Doubt, Throw it Out!

For additional information on food safety during an emergency, call the toll-free USDA Meat and Poultry Hotline at 1-888-MPHotline (1-888-674-6854); for the hearing-impaired (TTY) 1-800-256-7072.

The Hotline is staffed by food safety experts weekdays from 10 a.m. to 4 p.m. Eastern time. Food safety recordings can be heard 24 hours a day using a touch-tone phone. The media may contact the USDA Meat and Poultry Hotline at (301) 504-6258. Information is also available from the FSIS Web site: http://www.fsis.usda.gov

FOOD SAFETY REMINDERS FOR WEATHER EMERGENCIES

Real - http://www.usda.gov/agency/oc/bmtc/audio/real/RCN1MG.RA
MP3 - http://www.usda.gov/agency/oc/bmtc/audio/mp3/RCN1MG.MP3
WAV - http://www.usda.gov/agency/oc/bmtc/audio/wave/RCN1MG.WAV
ACTUALITY: NEEDS DURING A WEATHER EMERGENCY Real - http://www.usda.gov/agency/oc/bmtc/audio/real/RCN1MH.RA
MP3 - http://www.usda.gov/agency/oc/bmtc/audio/mp3/RCN1MH.MP3
WAV - http://www.usda.gov/agency/oc/bmtc/audio/wave/RCN1MH.WAV
ACTUALITY: MEAT AND POULTRY HOTLINE Real - http://www.usda.gov/agency/oc/bmtc/audio/real/RCN1MI.RA
MP3 - http://www.usda.gov/agency/oc/bmtc/audio/mp3/RCN1MI.MP3
WAV - http://www.usda.gov/agency/oc/bmtc/audio/wave/RCN1MI.WAV

For Further Information, Contact:
FSIS Congressional and Public Affairs Staff
Phone: (202) 720-9113
Fax: (202) 690-0460

Servicio de Inocuidad e Inspección de los Alimentos
Departamento de Agricultura de los Estados Unidos

AVISO de ALERTA del USDA para el CONSUMIDOR

Cómo Mantener los Alimentos Sanos Durante una Emergencia

http://www.fsis.usda.gov/OA/news/2003/weatheradv_sp.htm
Accessed: October 22, 2003

Washington, 17 de setiembre, 2003 – El Departamento de Agricultura de los Estados Unidos (USDA, por sus siglas en inglés), en vista de la proximidad del huracán, está ofreciendo recomendaciones para minimizar la probabilidad de intoxicaciones alimentarias.

Pasos a seguir en preparación para una emergencia climática:

- Mantenga termómetros para aparatos domésticos en el refrigerador y el congelador. Estos termómetros indicarán la temperatura en caso de un corte de la electricidad y servirán de ayuda en la determinación de la inocuidad de los alimentos.
- Asegure que el congelador esté a 0ºF o más frío y que el refrigerador esté a 40ºF o más frío.
- Congele recipientes con agua para que ayuden a mantener los alimentos fríos en el congelador, refrigerador o neveras (hieleras) portátiles después del corte de la electricidad.
- Congele los alimentos refrigerados, como las sobras, leche y las carnes y aves frescas que no se necesiten inmediatamente; esto ayuda a mantenerlos a una temperatura adecuada por más tiempo.
- Tenga un plan de antemano y sepa donde se puede comprar hielo seco o bloques de hielo.
- Almacene los alimentos en las repisas que se mantendrán a salvo de las aguas contaminadas en caso de inundación.
- Tenga neveras portátiles a la mano para mantener fríos los alimentos refrigerados si el corte de la electricidad va a durar por más de cuatro horas. Compre o prepare cubitos de hielo y guárdelos en el congelador para utilizarlos en el refrigerador o una nevera portátil. Congele, de antemano, bloques de gel para usar en las neveras portátiles.
- Agrupe los alimentos en el congelador; esto ayuda a que se mantengan fríos más tiempo.

Pasos a seguir después de la emergencia climática:

- Mantenga las puertas del refrigerador y el congelador cerradas en la medida de lo posible para mantener las temperaturas frías.
- El refrigerador mantendrá los alimentos adecuadamente fríos alrededor de cuatro horas si no se abre la puerta. El congelador lleno mantendrá la temperatura adecuada aproximadamente 48 horas (24 horas si está a medio llenar) si se mantiene cerrado.
- Los alimentos se pueden volver a congelar sin peligro si todavía mantienen cristales de hielo en su interior o están a una temperatura de 40 ºF o más fría.
- ¡Nunca pruebe un alimento para determinar su inocuidad!
- Obtenga hielo seco o en bloques para mantener el refrigerador y el congelador tan fríos como sea posible si el corte de la electricidad va a durar por tiempo prolongado. Cincuenta libras de hielo seco mantendrán por dos días un congelador de 18 pulgadas cúbicas que esté lleno.
- Si la electricidad ha permanecido cortada por varios días, verifique la temperatura del congelador con un termómetro para aparatos domésticos. Si los alimentos aún contienen cristales de hielo o se mantienen a una temperatura de 40ºF o menor, éstos se mantendrán inocuos.

- Si no se ha mantenido un termómetro en el congelador, examine cada paquete de alimento para determinar su inocuidad. Si el alimento todavía contiene cristales de hielo, estará sano.
- Deseche los alimentos perecederos que hayan estado refrigerados, tales como carnes, aves, pescados, quesos blandos, leche, huevos, sobras y alimentos de la fiambrería, después de cuatro horas sin electricidad.
- Beba solamente agua embotellada si ha ocurrido inundación.
- Deseche todo alimento que haya estado en contacto con las aguas de la inundación, a incluir alimentos enlatados. Deseche las tablas de picar de madera, utensilios de plástico, biberones y chupones (chupetas).
- Lave meticulosamente los moldes de metal, platos de cerámica y demás utensilios que hayan entrado en contacto con las aguas de la inundación. Use agua caliente y jabón y esterilícelos mediante el hervido en agua limpia o la inmersión por 15 minutos en una solución de una cucharadita de blanqueador (lejía) en un cuarto de galón de agua.

¡ Si en la duda perdura, tírelo a la basura !

Para información adicional sobre inocuidad alimentaria durante una emergencia, llame gratis a la Línea de Información sobre Carnes y Aves del Departamento de Agricultura de los EE.UU. al 1−888−674−6854; para personas con dificultad auditiva (TTY) 1−800−256−7072

El personal de la Línea de Información está compuesto por expertos en inocuidad alimentaria que contestan las llamadas de lunes a viernes desde las 10 a.m. hasta las 4 p.m. hora del este. Consejos grabados sobre inocuidad alimentaria se pueden escuchar durante las 24 horas del día usando un teléfono de botones. La prensa puede llamar a la Linea de Información al 1-301-504-6258. También se puede encontrar información en la página electrónica: http://www.fsis.usda.gov.

Enlaces para las entrevistas radiales - Formatos Real Audio, MP3 y WAV

Los puntos para recordar sobre inocuidad alimentaria en caso de emergencias climáticas
- Real - http://www.usda.gov/agency/oc/bmtc/audio/real/RCN1MG.RA
- MP3 - http://www.usda.gov/agency/oc/bmtc/audio/mp3/RCN1MG.MP3
- WAV - http://www.usda.gov/agency/oc/bmtc/audio/wave/RCN1MG.WAV

Las necesidades reales en caso de emergencias climáticas
- Real - http://www.usda.gov/agency/oc/bmtc/audio/real/RCN1MH.RA
- MP3 - http://www.usda.gov/agency/oc/bmtc/audio/mp3/RCN1MH.MP3
- WAV - http://www.usda.gov/agency/oc/bmtc/audio/wave/RCN1MH.WAV

Las realidades y la Línea de Información sobre Carnes y Aves
- Real - http://www.usda.gov/agency/oc/bmtc/audio/real/RCN1MI.RA
- MP3 - http://www.usda.gov/agency/oc/bmtc/audio/mp3/RCN1MI.MP3
- WAV - http://www.usda.gov/agency/oc/bmtc/audio/wave/RCN1MI.WAV

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Progress Report to Secretary Tommy G. Thompson: Ensuring the Safety and Security of the Nation's Food Supply

July 23, 2003
http://www.fda.gov/oc/initiatives/foodsecurity/default.htm

Message from the Commissioner of Food and Drugs

On July 23, 2003, the Food and Drug Administration (FDA) submitted to the Department of Health and Human Services Secretary Tommy G. Thompson this progress report entitled, "Ensuring the Safety and Security of the Nation's Food Supply," which summarizes the leadership demonstrated at FDA in combating the terrorist threat to foods.

FDA is responsible for ensuring the safety and security of 80% of the U.S. food supply. FDA's legislative mandate is to protect the public health by ensuring the safety of the production, processing, packaging, storage, and holding of domestic and imported food except those products (meat, poultry, and processed egg products) that are under the jurisdiction of the U.S. Department of Agriculture.

Although food safety and security are different aspects of food protection, they are inherently connected. FDA, at the direction of the Department of Health and Human Services (DHHS), has established a 10-Point Program for ensuring the safety and security of the food supply. Based on activities in FDA's 10-Point Program, the Agency is employing overall strategies to (1) develop increased awareness among federal, state, local, and tribal governments and the private sector by collecting, analyzing, and disseminating information and knowledge (Awareness); (2) develop capacity for identification of a specific threat or attack on the food supply (Prevention); (3) develop effective protection strategies to "shield" the food supply from terrorist threats (Protection); (4) develop capacity for a rapid, coordinated response to a foodborne terrorist attack (Response); and (5) develop capacity for a rapid, coordinated recovery from a foodborne terrorist attack (Recovery).

Within the food safety and security strategies, FDA's program features 10 areas of focus, based on the following principles:

Food security and safety are integrated goals. By building upon the Nation's core food safety/ public health systems and expertise, while strengthening expertise and capabilities needed to address the terrorist threat, FDA is enhancing food security and is improving food safety in the process.

The food safety and security system is comprehensive, addressing the full range of assessment, prevention, and response needs, throughout the food production and distribution chain. The system must be efficient and in the context of both safety and security, address the most significant threats first whenever possible.

The food safety and security system is also built on a solid foundation of a national partnership with other entities involved in food safety and security that fully integrates the assets of state, local and tribal governments, other federal agencies, and the private sector.
Americans must have confidence that the Government is taking all reasonable steps to protect the

food supply, and is providing Americans with timely and relevant information about threats and will provide timely and relevant information about an attack if one occurs.

The events of September 11, 2001, heightened the nation's awareness and placed a renewed focus on ensuring the protection of the nation's critical infrastructures. A terrorist attack on the food supply could pose both severe public health and economic impacts, while damaging the public's confidence in the food we eat. Several food incidents since the fall of 2001 highlight the significance of FDA's food security activities. In the fall of 2002, a competitor of a restauranteur in China added a chemical compound to his competitor's food and killed dozens of people and sent hundreds more to hospitals. Also in the fall of 2002, three individuals were arrested in Jerusalem for allegedly planning to carry out a mass poisoning of patrons at a local café. One of the arrested individuals worked as a chef at the café. In January 2003, several individuals were arrested in Britain for plotting to add ricin to the food supply on a British military base Each of these incidents shows the potential for the nation's food supply to be used in an attack.

Even before September 11, HHS was taking steps to improve food security. As part of the initial response to these heightened concerns after September 11, Congress provided FDA with new statutory authorities and some additional resources for food inspection. As a result of new threats to the food supply and new opportunities, FDA has made fundamental changes in how we implement our mission of protecting our food supply, so that all Americans can have confidence that their foods are not only safe but also secure. The attached 10-Point Program reflects a risk-based strategy to achieve the greatest food security and safety improvements with the least additional costs or food restrictions for consumers. In these efforts, FDA will continue to work with the White House Homeland Security Council, the United States Department of Agriculture (USDA), and the Department of Homeland Security (DHS) to further enhance our ability to detect, deter, and respond to an attack on our food supply.

Mark B. McClellan, M.D., Ph.D.

"Securing our food supply against terrorist threats is one of our most important public health priorities, especially at a time of heightened alert," said Tommy G. Thompson, Secretary of Health and Human Services.

Food Safety and Security Progress: A 10-Point Program
FDA Food Security Strategy

In the months before and after Sept. 11, 2001, Secretary Thompson led the effort to encourage Congress to increase FDA funding to protect the nation's families from an attack on the food supply. In fiscal years 2002 and 2003, Congress enacted more than $195 million for food safety programs, allowing FDA to hire 655 new food personnel and conduct more than double the previous number of food import examinations. In President Bush's fiscal year 2004 budget, the Department of Health and Human Services (DHHS) is requesting $116.3 million, an increase of $20.5 million over FY 2003, to further protect the nation's food supply.

FDA 10-Point Program	Awareness	Prevention	Preparedness	Response	Recovery
Stronger FDA-New Staff	X	X	X	X	X
Imports - Strategic Approach		X	X		
Bioterrorism Act Regulations		X	X	X	
Industry Guidance and Preventive Measures	X	X	X		
Vulnerability and Threat Assessments	X	X	X		
Operations Liberty Shield	X	X	X		
Emergency Preparedness and Response	X			X	X
Laboratory Enhancements		X	X	X	X
Research		X	X	X	X
Interagency and International Communication and Collaboration	X	X	X	X	X

The Agency is employing overall strategies to (1) develop increased awareness among federal, state, local, and tribal governments and the private sector by collecting, analyzing, and disseminating information and knowledge (Awareness); (2) develop capacity for identification of a specific threat or attack on the food supply (Prevention); (3) develop effective protection

strategies to "shield" the food supply from terrorist threats (Preparedness); (4) develop capacity for rapid, coordinated response to a foodborne terrorist attack (Response); and (5) develop capacity for rapid, coordinated recovery from a foodborne terrorist attack (Recovery).

Within the food safety and security strategies, FDA's program provides 10 areas of focus. The table below illustrates FDA's 10-Point Program and how each program area fits within the overall food safety and security strategies.

FDA has worked and continues to work closely with the states and other food safety, law enforcement, and intelligence agencies to collaborate on research, emergency response, and information exchange, all of which significantly strengthen the Nation's food safety and security system.

Strategies

Progress and Next Steps

Stronger FDA - New Staff

In the wake of September 11, 2001, HHS, working with bipartisan Congressional support and action, obtained funding for the FDA. FDA moved expeditiously and quickly to establish this additional investigative and scientific team by rapidly hiring and training 655 additional field personnel. Of the 655, 97% are allocated to food safety field activities: 300 support the conduct of consumer safety investigations at U.S. ports of entry, 100 support laboratory analyses on imported products, 33 are for criminal investigations of import activities, and the remaining personnel support domestic efforts.

The Public Health Security and Bioterrorism Preparedness and Response Act (Bioterrorism Act) was enacted in June 2002 and by the end of the year, FDA had started to place additional, trained investigators and analysts at targeted locations. Training of these new personnel has been paramount. Utilizing the platform provided by the Office of Regulatory Affairs' University (ORA U), FDA has retooled its existing "new hire" curriculum for investigators and its "new hire" curriculum for analysts so that new investigators and new analysts are prepared to do basic work within three months of employment. This basic investigatory work includes recall audits, sample collections, complaint follow-up investigations, and import exams. The basic analytical work includes basic lab operations and sample preparation. The curricula continue through the first 12 months of employment, culminating in an on-the-job audit of performance where the new employee demonstrates job competency to an auditor using standardized criteria.

U.S. borders are flooded with FDA-regulated imports from all over the world, and the continuous threat of terrorism requires FDA to remain vigilant in its effort to retain a competent, trained workforce if we are to maintain a high level of readiness. With FDA's limited resources to meet the challenge of assuring the food safety and security for more than 6 million entries per year, FDA must strategically develop hiring, targeting resources and succession planning to be prepared in the event of a terrorist attack.

FDA not only mobilized new staff but redirected, trained current investigators and scientists to integrate and strengthen its food safety and security mission and ensured that the agency has the necessary scientific and logistical expertise to respond to an event that could threaten the safety and security of the food supply. FDA has hired or re-trained scientific experts in biological, chemical and radiological agent research, detection methodology, preventive technologies and acquired substantial knowledge of these agents to help support domestic and import activities. FDA's Office of Regulatory Affairs (ORA) has developed a succession plan to ensure that the

agency will continue to have highly trained and competent scientists, investigators, analysts, and managers to accomplish the agency's overall mission of consumer protection. FDA realizes that recruitment and retention of our highly skilled and sometimes very specialized workforce requires thoughtful planning so that we will be ready to effectively and efficiently meet the future challenges FDA faces.

Imports - Strategic Approach

FDA continues to adjust its import program via the development of an Import Strategic Plan (ISP) to reflect the changing nature of risks and trade associated with imported goods. This approach encompasses and addresses the full "life-cycle" of imported products. As part of the ISP, FDA is assessing information derived from foreign and domestic inspectional operations, adverse events, consumer complaints, recall activities, and information technology. The goal of the ISP is to better protect the public health and safety by decreasing the risk that unsafe, ineffective, or violative products will enter U.S. commerce through our borders, ports, and other import hubs. Moreover, when implemented, the ISP will provide FDA with the critical flexibility it needs to shift resources as import trends alter the risks and change priorities for public health and safety protection.

Historically, the volume of U.S. imports of FDA-regulated products was relatively small and consisted of raw ingredients and bulk materials intended for further processing or incorporation into finished products. Therefore, FDA could rely more heavily on physical examination and domestic inspections to ensure that imported raw ingredients and bulk materials were properly handled, received, quarantined, released and processed according to good manufacturing practices and sanitation principles.

Even with the recent increases of personnel for counter terrorism efforts, border inspections cannot manage the changes in the nature of risks and trade. FDA is taking steps to implement a risk-based approach towards covering the importation of FDA-regulated goods. These proactive steps will assist FDA in identifying patterns of transportation while goods are in international streams of commerce; increase our ability to conduct effective, efficient foreign inspections; and will aid FDA in making admissibility decisions before goods enter domestic commerce. Moreover, the risk-based approaches we are contemplating include exploring the feasibility of forming regulatory partnerships to provide better information to FDA - and, ultimately, better protection to U.S. consumers.

FDA is supporting this enhanced import strategic plan by providing a greater import presence at our nation's borders. FDA is enhancing our capacity and capability to perform normal import operations such as sample collection and analysis, field examinations, and inspections across all our programs. In 2001, FDA provided coverage at about 40 ports of entry. By 2002, FDA had more than doubled its presence to 90 ports of entry.

In addition, since 2001, FDA more than quintupled the number of food import examinations. In 2001, FDA conducted 12,000 food exams. FDA has conducted over 62,000 food exams already this fiscal year and has surpassed its 2003 year-end goal of 48,000 food exams. This increased coverage was due to redirecting resources dedicated to assure increased import coverage during Operation Liberty Shield when the Nation was at a heightened security alert.

FDA is working to increase import filer evaluations to ensure integrity of importers and import entry data and to increase collections of samples for laboratory analysis.

FDA is working on additional enhancements to the Operational and Administrative System for Import Support (OASIS) to include real-time screening with multi-agency import databases to help target inspection resources.

Bioterrorism Act Regulations

FDA is on schedule to publish four major new regulations in accordance with provisions of the Bioterrorism Act. The agency intends to publish two final rules in October of this year and two additional final rules by the end of this year. These rules implement new authority that FDA received in the Bioterrorism Act and, are one of the most significant enhancements of FDA's statutory authority to keep food imports secure

On February 3, 2003, FDA and the Department of Treasury jointly published in the Federal Register a proposed regulation implementing the provisions in the Bioterrorism Act that would require owners, operators, or agents of a foreign or domestic facility where food is manufactured/ processed, packed, or held to submit a registration to the FDA that includes basic information about the facility, emergency contact information, and the categories of food the facility handles.

On February 3, 2003, FDA and the Department of Treasury also jointly published in the Federal Register a proposed regulation implementing the provisions in the Bioterrorism Act that would require FDA to receive prior notice before imported food arrives at the U.S. port of arrival.

On May 9, 2003, FDA published in the Federal Register a proposed regulation implementing the provisions in the Bioterrorism Act that would require manufacturers, processors, packers, transporters, distributors, receivers, holders, and importers of food to keep records identifying the immediate previous source from which they receive food, as well as the immediate subsequent recipient, to whom they sent food.

On May 9, 2003, FDA also published in the Federal Register a proposed regulation implementing the provisions in the Bioterrorism Act related to FDA's new authority to detain any article of food for which there is credible evidence or information that the article poses a threat of serious adverse health consequences or death to human or animals. The administrative detention authority granted to FDA under the Bioterrorism Act is self-executing and currently in effect.

FDA published each of the regulations with a 60-day comment period. We received many comments on each rule that suggested ways the rules could be improved to minimize the impact on commerce, while accomplishing the statutory objective. FDA is considering these comments and will make appropriate changes to the rules before issuing them in final form. These rules primarily are designed to give FDA additional information about food intended for consumption in the United States and the facilities that handle that food. As such, these statutory provisions do not raise the "science issues" as many of our rulemakings do (nor did the Agency receive comment in that area), or as other provisions in the Bioterrorism Act do.

FDA held two major satellite downlinks to explain the proposed regulations to affected parties around the world. The first was held on January 29, 2003 and discussed food facility registration and prior notice proposed requirements. The second was held on May 7, 2003 and discussed the proposed administrative detention procedures and the proposed requirements governing the establishment and maintenance of records. The broadcasts were made available in English, Spanish and French and were viewed at over 20 FDA sites, in Canada, Mexico, and South America. Viewers included importers, brokers, manufacturers and processors of foods and feeds, transporters, state officials, foreign embassy officials, foreign governments, and representatives

of trade associations. In addition, the agency has conducted outreach regarding these regulations in other forums.
FDA has trained a cadre of speakers and has participated in over 80 meetings in many venues such as the Alliance for Food Safety and Security in Washington, DC, the World Trade Organization in Geneva, Switzerland, and at a meeting hosted by the government of Japan in Tokyo, Japan, giving presentations and talks on the proposed rules. FDA senior officials involved in developing the rules also attended meetings with government officials and industry representatives in Canada, Mexico, and the European Union.

FDA is intent on reviewing the many comments concerning the proposed regulations and is taking steps to implement these regulations with recognizing current business practices and emphasizing efficiency to implement and meet the intent of the Act.

FDA also developed and conducted demonstrations of the rapid, easy-to-use on-line registration system that companies can use to register starting in mid-October 2003.

FDA is working with the Bureau of Customs and Border Protection (CBP), to streamline the implementation of the prior notice requirements of the Bioterrorism Act. This will allow food importers to provide required information on food imports to both agencies using a single IT process.

FDA is working to finalize these regulations. We are currently considering all the timely comments that were submitted, and where appropriate, making appropriate changes to the regulations for food facility registration, prior notice, establishment and maintenance of records, and administrative detention before issuing them in final form. FDA is planning to host satellite downlinks and regional meetings to assist stakeholders in understanding and complying with the final rules. FDA is also developing "user-friendly" materials to serve as aids and to assist stakeholders.

Industry Guidance and Preventive Measures
On January 9, 2002, FDA published in the Federal Register and made available on its Website two draft guidance documents related to food security. The first, "Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance," is designed to aid operators of food establishments. The second, "Importers and Filers: Food Security Preventive Measures Guidance," is designed to help food importers. Each document recommends the types of preventive measures that companies can consider to minimize the risk that food under their control will be subject to tampering or criminal or terrorist actions. Following public comment, FDA issued final versions of the guidance documents on March 21, 2003, in conjunction with FDA's efforts during Operation Liberty Shield. We discuss Operation Liberty Shield in more detail later in the document.

On March 21, 2003, FDA published in the Federal Register and made available on its Website two additional draft guidance documents related to food and cosmetic security. The first, "Retail Food Stores and Food Service Establishments: Food Security Preventive Measures Guidance," is designed to aid operators of food retail food stores and food service establishments. The second, "Cosmetic Processors and Transporters: Cosmetic Security Preventive Measures Guidance," is designed to help operators of cosmetic establishments. Each document recommends the types of preventive measures that companies can consider to minimize the risk that food or cosmetics under their control will be subject to tampering or criminal or terrorist actions.

FDA developed and made available on July 11, 2003, an additional guidance document related to food security preventive measures for milk, "Guidance for Industry: Dairy Farms, Bulk Milk Transporters, Bulk Milk Transfer Stations and Fluid Milk Processors; Food Security Preventive Measures Guidance."

FDA, in collaboration with the Technical Support Working Group (TSWG) of the Department of Defense, is working with the John A. Volpe National Transportation Systems Center in Cambridge, Massachusetts on a project related to the security of domestic and overseas transport of food.

TSWG and FDA are also working with St. Joseph's University, Philadelphia, Pennsylvania, to develop an accredited modular food security and protection training curriculum for both academics and professionals that is capable of being delivered in a traditional classroom setting as well as via CD-ROM and though web-based delivery formats. Industry representatives at the first user's group meeting in June 2003 confirmed the value of the training.

TWSG and FDA are working with Sensor Research and Development, a small company in Orono, Maine, to develop a prototype of a food pathogen detector (MIPSTRIP).

Consumers play a critical role in preventing illness due to food tampering. FDA encourages consumers when shopping to carefully examine all food product packaging, check any anti-tampering devices on the packaging, not to purchase products if the packaging is open, torn, or damaged, not to buy products that are damaged or that look unusual and to check the "sell-by" dates. Consumers are also encouraged to carefully inspect products at home when opening the container and to never eat food from products that are damaged or that look unusual.

Vulnerability and Threat Assessments

Using the methodology called Operational Risk Management (ORM), FDA developed a vulnerability assessment for foods. The assessment evaluates the public health consequences of a range of product-agent scenarios associated with potential tampering, criminal, malicious, or terrorist activity. This relative risk ranking is designed to facilitate decision-making about the assignment of limited federal, state, and local public health resources to minimize such risks. It is also designed to assist the food industry in identifying areas where enhancements in preventive measures could increase the security of the food supply. This internal assessment identified a number of food/agent combinations that FDA is focusing on to implement shields for protecting those commodities. These shields will be implemented in partnership with our regulatory counterparts and industry.

FDA initiated and awarded a task order to the Institute of Food Technologists (IFT) to conduct an in-depth review of ORM and provide a critique on its application to Food Security. As part of this review, IFT was asked to apply ORM to food and to evaluate the relative public health consequences of a range of product-agent scenarios. This review validated FDA's vulnerability assessment process and provided additional information on the public health consequences of a range of product, agent, and process scenarios. This assessment affirmed the food/agent combinations identified in the FDA ORM assessment and identified additional commodities to consider for shield implementation.

As an additional step, on June 4, 2003, FDA awarded an additional task order to IFT, requesting that IFT conduct an in-depth review of preventive measures that food processors may take to reduce the risk of an intentional act of terrorism or contamination. The review will assess ways to

prevent or reduce the risk of contamination of processed food and will provide information on various research needs related to elimination or reduction of the risks. IFT will provide information on various processing technologies that might be used for eliminating or reducing the risk of an intentional act of terrorism or contamination for several commodity, agent, and processing combinations.

FDA also contracted with Battelle Memorial Institute to conduct a "Food and Cosmetics, Chemical, Biological, and Radiological Threat Assessment". The assessment affirmed the findings of the FDA/CFSAN Operational Risk Management Assessment, provided an additional decision-making tool for performing risk assessments, incorporating a Hazard Analysis Critical Control Points (HACCP) type approach, and made a number of recommendations about research needs, the need for enhanced laboratory capability and capacity, and the need for enhanced partnerships between federal, state, and local governments to ensure food security.

FDA provides regular updates to Congress about threat assessments and vulnerabilities related to the safety and security of the U.S. food supply. FDA will be providing to Congress the threat assessments conducted by FDA, IFT and the Battelle Memorial Institute.

FDA is conducting additional assessments of the vulnerability of FDA-regulated foods to intentional contamination with biological, chemical and radiological agents. These assessments use processes adapted from techniques developed by the U.S. Department of Defense for use in assessing the vulnerabilities of military targets to asymmetric threats. Results of the assessments will be used to develop countermeasures, identify research needs, and provide guidance to the private sector

Operation Liberty Shield: FDA Food Security Enhancements in Times of Heightened Alert

In March 2003, the United States government launched Operation Liberty Shield to increase security and readiness in the United States at a time of elevated risk for a terrorist attack. Operation Liberty Shield, a comprehensive national plan of action to protect many of America's critical infrastructures, was a unified operation coordinated by the Department of Homeland Security that integrated selected national protective measures with the involvement and support of federal, state, local, and private responders and authorities from around the country. Operation Liberty Shield was designed to provide increased protection for America's citizens and infrastructure while maintaining the free flow of goods and people across our border with minimal disruption to our economy and way of life. FDA has established protocols, trained staff and deployed supplies and equipment for future and similar elevated threat level actions. A key component of Operation Liberty Shield was increasing and targeting surveillance of both domestic and imported food. The Agency initiated the following activities:

FDA issued new industry guidance documents on security measures and encouraged industry to voluntarily assess their security measures in response to an increased threat level. These guidance documents were discussed earlier in the document.

FDA held a series of conference calls to brief state regulatory agencies, industry trade associations, consumer groups, and their federal counterparts, on Operation Liberty Shield and to request their assistance in distributing the food security guidance documents to domestic facilities and the portion of the import community that handles food products.

FDA increased its surveillance of the domestic food industry, during Operation Liberty Shield,

by conducting 844 inspections of domestic firms based on risk/threat assessments with a focus on enhancing awareness of food security at these facilities by providing copies of appropriate food security guidance documents. These investigations targeted examinations of specific commodities based on risk/threat assessments and sampled specific commodities based on risk/threat.

FDA increased its monitoring of imported foods, during Operation Liberty Shield, by conducting increased examinations of specific imported commodities based on FDA's risk/threat assessments; enhancing the import communities' awareness of food security at ports by providing copies of FDA's food security guidance documents and sampling imported foods based on risk/ threat assessments. FDA collected and analyzed 387 import samples for chemical and microbiological contaminants.

FDA conducted domestic and import reconciliation exams to confirm that regulated commodities were what they purported to be, exposed unexplained differences between associated documentation and the product, and uncovered signs of tampering or counterfeiting.
FDA increased joint activities with federal, state, and local partners to help ensure a safe and secure food supply, including working with the Centers for Disease Control and Prevention to ensure that outbreaks or unusual patterns of illness or injury are quickly investigated.

Likewise, USDA undertook similar food security measures and activities for its regulated industries including meat, poultry and processed egg products. Thus, in combination, FDA and USDA comprehensively covered the U.S. food supply.

Emergency Preparedness and Response
FDA has established an Office of Crisis Management (OCM) to coordinate the preparedness and emergency response activities of the five FDA Centers, ORA and their Offices working with their federal, state and local counterparts that may be engaged in a variety of different emergencies involving FDA regulated products and/or the need to provide medical countermeasures. Within OCM, the FDA Emergency Operations Center serves as the chief communications node and point of contact within FDA.

Over the past two years, FDA has participated in and conducted multiple emergency response exercises. Frequently, these exercises are coordinated with other federal and state agencies. In both exercises and everyday issues, FDA's OCM works closely with the Department of Health and Human Services/Office of Public Health Emergency Preparedness (OPHEP) and the Secretary's Command Center (SCC). This relationship facilitates communication between all HHS Operating Divisions, the Department, and other federal agencies and Departments, including the Department of Homeland Security. In particular, FDA has focused on strengthening its working relationship with USDA by joint testing of several response plans in an exercise environment. In May 2003, FDA participated in the TOPOFF 2 terrorism exercise, a national, full scale, fully functional exercise intended to simulate two separate terrorist acts that had implications for food products (e.g., the possibility of food contamination by radiation), as well as the ensuing response by federal, state, and local governments.

FDA has also signed an Inter Agency Agreement (IAG) with the U.S. Army to design and develop two mobile laboratories to be deployed at borders, ports, or other locations, to provide timely and efficient analyses of samples being offered for import into the U.S. and/or in the event of terrorist activity. The mobile laboratories are expected to be ready for deployment in 2004.

Within current resources, FDA is assessing its ability to respond to high-risk product-agent

scenarios and for what sustained period. This includes a review of our current scientific capabilities that may be available for extramural sources (academia, DoD, etc.) and efforts to enhance the nation's food laboratory capacity at federal, state and local facilities to conduct rapid, accurate tests to determine quickly the precise extent of food contamination in the event of an actual or suspected terrorist attack.

Laboratory Enhancements
Methods Development
FDA has redirected laboratory staff to develop laboratory methods for priority biological and chemical agents in food. Methods have been developed for the highest priority select agents.

FDA has reviewed and modified current regulatory analytical methods for their applicability to terrorism related samples. Methods have been modified to provide more rapid analysis while maintaining practical sensitivity.

FDA is enhancing its capacity to develop methods that can be used for rapid analysis of suspect foods for select agents or toxins, including the development of rapid methods that can be deployed and used in a field setting.

FDA is working to adapt an FDA toxin screening method for application as a surveillance tool.

FDA has established an IAG with Edgewood Arsenal and a task order contract with Midwest Research Institute for the validation of methods for the detection of microbiological agents in foods.

FDA has partnered with the Department of Defense to develop and validate methods to detect agents most likely to be used in a terrorist attack on the food supply, and engaged in interagency agreements that would allow the Department of Defense to provide laboratory support in the event of an attack.

Under contract to FDA, the New Mexico State University (NMSU) Physical Science Laboratory (PSL) is evaluating rapid test methods for microbiological analyses of produce samples. NMSU's evaluation includes the assessment of rapid test methods for a particular analyte(s) or food commodity - which is required prior to the agency adoption of any kit for use in the regulatory arena.

Network Development
FDA has worked with CDC, USDA, EPA, DOE and the States to initiate development of a nationwide Food Emergency Response Network (FERN). FERN is a network of state and federal laboratories that is committed to analyzing food samples in the event of a biological, chemical, or radiological terrorist event in this country. As of June 2003, there were 63 laboratories participating in the FERN network, representing 27 states and 5 federal agencies. Following the events of September 11, 2001, FDA took aggressive action to develop this network building on then-existing laboratory capabilities. FDA is working to add additional food laboratories to the FERN. Furthermore, FDA will work with CDC and the states to improve laboratory capacity to enhance response capability for food security concerns. With CDC grant funds, states are initiating additional activities to increase lab capacity for food-related emergencies.

FDA has made available methods for the isolation and detection of high-priority microorganisms and chemical agents not usually found in food that can be utilized by Laboratory Response

Network (LRN) and FERN laboratories on a password protected website.

FDA has used emergency funding to purchase rapid method test kits for chemical and microbiological agents and has distributed the materials to laboratories within FERN

Ninety five laboratories representing 48 states are participating in the Electronic Laboratory Exchange Network (eLEXNET), the nation's first seamless, integrated, web-based data exchange system for food testing information. eLEXNET allows health officials at multiple government agencies engaged in food safety activities to compare, share, and coordinate laboratory analysis findings on food products. At its inception in 2000, eLEXNET included a mere 8 labs from 7 states and was capable of tracking a sole analyte. Whereas FERN laboratories are involved in the actual analysis of food samples, eLEXNET provides a forum for the exchange of laboratory data. FDA is continuing efforts to expand eLEXNET to provide better nationwide data on food product analyses by regulatory agencies.

Staff Development and Training
FDA has trained its staff as well as staff from USDA, state food laboratories and the CDC Laboratory Response Network public health laboratories in the analysis of foods for several microorganisms.

Research
HHS Secretary Tommy Thompson and FDA Commissioner Dr. Mark McClellan announced the commitment of $5M in supplemental funding from the Office of Management and Budget (OMB) to support FDA's food security research initiative. The FDA plans to focus this new food security research thrust on three broad areas: (1) development of prevention and mitigation technologies/ strategies, (2) the elucidation of agent characteristics needed to develop these prevention technologies, and (3) the development of means for continuously assessing foods (raw or finished product) for contamination with chemical, microbiological, and radiological agents. This integrated program will draw upon all three components of FDA's research infrastructure: its intramural research capabilities, its collaborative Centers of Excellence (e.g., National Center for Food Safety and Technology, Joint Institute for Food Safety and Applied Nutrition, National Center for Natural Products Research), and extramural research programs that provides competitive research contracts and grants. Specific projects will involve: determining the stability of select chemical threat agents in foods and the impact of processing operations; the development of enrichment techniques for the isolation of select microbial agents from high priority foods; the development of prevention/mitigation strategies for intentional contamination of animal feed used for food-producing animals; the development of risk assessment tools for assessing critical control points within a food security/safety system; the development of methods for decontaminating food processing facilities, retail establishment s , and transportation equipment that have been exposed to microbiological, chemical, or radiological agents as a result of a terrorism incident involving foods; the acceleration of the development of rapid, field deployable analytical methods for detecting select agents in foods; and the development of a PC-based Analytical Modeling Tool to facilitate rapid response to food security and safety emergencies.

Intramural Program
Although modern technology has considerable potential to improve our ability to keep the nation's food supply secure, research on food security is a relatively new concept. To take advantage of the opportunities for making foods safer and more secure through research and development of new technologies, FDA, HHS, and the Administration are taking unprecedented steps to develop this new area of research. In particular, FDA has already redirected existing

research staff to ensure that appropriate resources are focused on key priority food safety and security issues. FDA has over 25 intramural research projects ongoing related to food security.

Steps Toward Establishment of Extramural Food Security Research Program
On June 25, 2003, FDA published in the Federal Register a Request for Applications (RFA) entitled "Food Safety, Nutrition, Bioterrorism, Agricultural Research, Medical, Analytical Methods and Risk Assessment." The RFA requested applications to support collaborative research efforts and to complement and accelerate ongoing research in four project areas: (1) development and rapid analytical screening methods for the detection of pathogens that are not usually associated with food and foodborne illness at a contamination level of 100 to 10,000 microbial pathogens/gram of food without pre-growth or selective enrichment; (2) development of PCR-based methods for rapid confirmatory identification of pathogens that are not usually associated food and foodborne illness; (3) development of rapid screening methods capable of detecting a broad range of non-traditional chemical and toxin adulterants; and (4) development of improved equipment, software, procedures, and/or methods for determining radionuclide contamination in foods.

New Research Collaborations
FDA is collaborating with the National Institutes of Health (NIH) on a joint project to fund critical research on the thermal stability of key select agent(s) in high risk food(s).

FDA has initiated cooperative research programs with the National Center for Food Safety and Technology (NCFST) on the impact of food processing on the stability of microbiological and chemical agents in foods under conditions that would occur in commercial operations.

FDA participates in the Technical Support Working Group (TSWG), the U.S. national forum that identifies, prioritizes and coordinates interagency and international research and development requirements for combating terrorism

The Joint Institute for Food Safety and Applied Nutrition (JIFSAN), a public-private partnership established between FDA and the University of Maryland in 1996, in collaboration with the US-Israel Binational Agricultural Research and Development (BARD) Fund held a food security conference, "Science and Technology Based Countermeasures to Foodborne Terrorism," on June 29 - July 2, 2003. The conference provided a forum to discuss the current state of knowledge about foodborne terrorism, including threat assessment methods, methods of detection, tracking, tracing, authenticating and anti-tampering technologies and hazard mitigation.

Establishing Broader Research Agenda
FDA is developing a broader research agenda to address critical research needs to aggressively meet food security challenges. The research would focus on three broad areas: (1) development of prevention and mitigation technologies/strategies, (2) the elucidation of agent characteristics needed to develop prevention technologies, and (3) the development of means for continuously assessing foods (raw or finished product) for contamination with chemical, microbiological, and radiological agents. These research needs are being prioritized into short, medium, and longer-term phases: (1) technological assessment and critical data deficiencies that can be addressed in the short-term (12 months), (2) critical knowledge deficiencies or technology applications that can be addressed with targeted research and development projects lasting 12-24 months, and (3) research and development that will require elucidation of new technologies or substantial extension of existing scientific knowledge (24 - 60 months). Such research is being planned as an integrated program that will draw upon all three components of FDA research infrastructure: its

intramural capabilities, its collaborative Centers of Excellence (e.g., National Center for Food Safety and Technology, Joint Institute for Food Safety and Applied Nutrition, and National Center for Natural Products Research), and extramural research program that provides competitive research contracts. FDA will also actively collaborate with other federal government research organizations, including NIH, USDA, and DoD.

Interagency and International Communication and Collaboration
Food security, like other aspects of protecting our Nation's critical infrastructures, requires effective and enhanced coordination across many government agencies at the federal, state, and local level. FDA's activities in public health security are coordinated through the Department of Health and Human Services (DHHS) Secretary's Command Center. This relationship facilitates communication between all HHS Operating Divisions, the Department, and other federal agencies and Departments, including Homeland Security. Some of these security steps facilitated by this coordination are outlined below.

FDA holds regularly scheduled interagency conference calls with representatives from USDA ¬Animal and Plant Health Inspection Service (APHIS) and FSIS|, CDC, Environmental Protection Agency (EPA), DoD, Department of Commerce, Tax and Trade Bureau, and the Bureau of Customs and Border Protection (CBP). FDA also regularly consults with its interagency partners.

On February 4, 2003, FDA, in conjunction with the National Association of State Departments of Agriculture (NASDA), the Association of State and Territorial Health Officials, USDA, and CDC, sponsored a one day executive level meeting with the Secretaries of State Departments of Agriculture and the State Departments of Health titled "Homeland Security - Protecting Agriculture, the Food Supply and Public Health - The Role of the States."

FDA is also actively promoting the commissioning by FDA of State secretaries of agriculture and health so they can receive and review food safety and security documents from FDA. This helps promote information sharing between States and FDA.

FDA is also represented on the White House Homeland Security Council's Interagency Food Working Group (IFWG). The IFWG includes representation from DHHS/FDA, USDA/FSIS, Department of Defense, Environmental Protection Agency, Department of Transportation, Central Intelligence Agency, Federal Bureau of Investigation, Department of Treasury, Federal Emergency Management Agency, and a variety of White House representatives. FDA is developing plans for improved laboratory preparedness, and product security, and is drafting a National Interagency Food Response Plan in coordination with states, industry, and food trade associations. FDA is represented on three IFWG subgroups: Laboratory Subgroup, Shields Subgroup, and Incident Command Subgroup.

As part of the Department-wide collaboration and effort to improve nationwide capacity, the Centers for Disease Control and Prevention (CDC) has initiated a cooperative agreement program and has made funds available to upgrade state and local jurisdictions' public health preparedness for and in response to bioterrorism, other outbreaks of infectious disease, and other public health threats and emergencies. CDC is making available $870 million this fiscal year. Awards will be made to address needs in seven focus areas: (1) Preparedness Planning and Readiness Assessment, (2) Surveillance and Epidemiology Capacity, (3) Laboratory Capacity - Biologic Agents, (4) Laboratory Capacity - Chemical Agents, (5) Health Alert Network/Communications and Information Technology, (6) Communicating Health Risks and Health Information

Dissemination, and (7) Education and Training. Improving laboratory capacity, including for food analysis, is an integral part of this effort.

FDA is working very closely with the Department of Homeland Security and the White House Homeland Security Council on a variety of issues. We are consulting with DHS and HSC on research initiatives, shield implementation, and seeking security clearances for appropriate individuals within the food industry in order to share classified information.

FDA has conducted numerous emergency response exercises with our federal counterparts to strengthen the federal response to a food incident. The Department of Health and Human Services has participated in several Deputy Secretary level exercises with USDA, DoD, EPA, CIA, and FBI to test our emergency response capabilities. TOPOFF 2 was an excellent example of interagency cooperation by USDA/FSIS sending representatives to the DHHS/Command Center and the FDA Emergency Operations Center.

Despite the comprehensive work that FDA has accomplished to date, there are additional steps that are being contemplated. These future projects are discussed below.

FDA is working with the Department of Homeland Security and USDA, to establish a Food Sector and a Food Information Sharing and Analysis Center (ISAC) to facilitate the overall protection of the food sector's critical infrastructure and to share information about vulnerabilities, threats, and incidents.
FDA is working closely with Canada and Mexico in an effort to assess and strengthen our public health and food security systems and infrastructure at our mutual borders. FDA and USDA are working with our Canadian and Mexican counterparts through bilateral workgroups to enhance existing partnerships, e.g. Global Health Security Action Group, forge new and improved food and agriculture security measures and systems covering prevention and preparedness; response to and recovery from potential threats.

FDA is collaborating with the Department of Homeland Security and USDA (Food Safety and Inspection Service) and has proposed projects for the prevention of and response to an intentional threat to the food supply.

SUMMARY
FDA thorough it's aggressive program, has made significant progress in strengthening the safety and security of the Nation's food supply.

Nearly 20% of all imports into the U.S. are food and food products. FDA anticipates that we will receive over 8 million food shipments from over 200,000 foreign manufacturers this year--a huge volume that continues to grow rapidly. To meet this challenge, FDA is providing a greater import presence. FDA has placed an additional 300 field personnel at U.S. ports of entry. FDA now has a presence at 90 ports of entry and quintupled the number of food import examinations it performed this year compared to 2001--FDA has exceeded its year-end goal of 48,000 by 14,000 food import examinations.

FDA is using risk-based strategies to provide better information and in its collaborative efforts with other entities. This includes working with foreign authorities and manufacturers to improve production and shipping practices abroad as an alternative to detailed inspections at the boarder. FDA is using better information on imports to focus border checks on products that present

significant potential risks and is working with producers to improve checks on the integrity of ingredients and to implement common-sense steps to reduce security risks.

FDA is on schedule to publish four major new regulations in accordance with provisions of the Bioterrorism Act that provide the agency with most significant enhancements to FDA's statutory authority to keep food imports secure. The agency intends to publish two final rules in October of this year and two additional final rules by the end of this year.

FDA has taken unprecedented steps to develop food security research. FDA has received $5 million in supplemental funding from OMB to support FDA's food security research initiative. FDA is using this supplemental funding to focus on three broad areas: development of prevention and mitigation technologies and strategies, elucidation of agent characteristics, and development of means for continuously assessing foods for contamination. FDA has redirected existing research staff to focus on key priority issues and has over 25 intramural research projects ongoing related to food security. FDA is developing a broader research agenda to address critical research needs to aggressively meet food security challenges including development of prevention and mitigation technologies/strategies, elucidation of agent characteristics needed to develop prevention technologies, and development of means for continuously assessing foods for contamination.

FDA remains dedicated to ensuring the safety and security of the nation's food supply. Americans depend on FDA to keep food safe and secure, and FDA will keep doing all we can to fulfill this critical mission.

Cruising with Confidence

http://www.fda.gov/fdac/features/2003/303_virus.html
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By Linda Bren
Shaking hands may be the conventional greeting for landlubbers, but on the high seas, the "forearm tap" has become popular. This greeting of knocking elbows together instead of shaking hands was encouraged by a number of cruise lines to raise awareness of the importance of personal hygiene on board ship, according to a representative for Carnival Cruise Lines.

Poor personal hygiene is the likely cause of gastrointestinal illness (gastroenteritis) on cruise ships, according to the Centers for Disease Control and Prevention (CDC). The CDC investigated 22 reports of gastroenteritis outbreaks aboard 18 cruise ships from Jan. 1, 2002, through Dec. 31, 2002. Of the 22 outbreaks, three were blamed on bacteria and seven could not be traced with certainty, but the remaining 12 were confirmed to be associated with noroviruses--a group of viruses that cause gastroenteritis, also known as Norwalk-like viruses.

Symptoms of norovirus infection include nausea, vomiting, diarrhea and stomach cramping that can last from 12 to 60 hours. The symptoms usually begin 24 to 48 hours after a virus is ingested. Although people may feel very ill and vomit frequently, norovirus infections are not considered serious in most individuals. But they may become serious in the very young, older people, and in those with weakened immune systems.

Noroviruses are found in the stool or vomit of infected people, and infection can spread in several ways:

- Eating food or drinking liquids that are contaminated with the virus
- Touching contaminated surfaces or objects and then placing your hands in or near your mouth
- Having direct contact with another person who is infected and showing symptoms (for example, sharing foods or eating utensils).

Viruses aren't the vacationer's only cause of gastrointestinal illness. "Travelers can also get diarrhea from bacterial infections," says Renata Albrecht, M.D., the director of the Food and Drug Administration's Division of Special Pathogen and Immunologic Drug Products. Bacterial infections usually go away over time without treatment, but doctors may prescribe antibiotics to treat some and shorten the duration of the diarrhea, says Albrecht. No medications are approved for preventing bacterial infection, nor are there medications that prevent or treat noroviruses.

Advice for Travelers
Frequent and thorough hand washing with warm, soapy water is the best prevention against gastroenteritis, says LeeAnne Jackson, Ph.D., a health science policy adviser in the FDA's Center for Food Safety and Applied Nutrition. Travelers who don't have ready access to soap and water may want to carry along a hand gel sanitizer, found in most supermarkets and drugstores. Jackson also advises travelers to choose foods and beverages carefully. Foods should be thoroughly cooked and served hot. Poor sanitation in some countries may lead to contaminated food and drink, which are the major sources of stomach or intestinal illness while traveling, according to the CDC. Just about any food can become contaminated if handled improperly, but items of particular concern include raw meat, raw seafood, green salads, and raw sprouts. "In

some countries, it's wise to steer clear of street food vendors, especially if they serve fresh-cut fruits," says Jackson, who advocates purchasing fruits whole, peeling them and cutting them up yourself.

Travelers should avoid unpasteurized milk or products made with unpasteurized milk, unpasteurized juices and ciders, says Jackson. Beverages that may be safer than tap water in some countries are hot beverages, such as coffee or tea made with boiled water, canned or bottled carbonated beverages, and beer and wine. Avoid ice made with tap water. Water on the surface of a beverage can or bottle may be contaminated, so wipe clean and dry the area of the container that will touch your mouth.

The Cruise Ship Connection

CDC investigators believe that most of the recent norovirus infections on cruise ships were spread person-to-person through hand-to-mouth activity. "We suspect that people are probably coming on board with the virus," says Dave Forney, chief of the CDC's Vessel Sanitation Program. "On a cruise ship, people are out and about in very public areas, and so we have this depositing of the virus on various surfaces that then would be easily picked up by others." Forney advises cruisers who are ill to avoid contact with other individuals and to report to the ship's medical facility. Unfortunately, many of them don't want to be told to stay in their cabins, adds Forney, so passengers spreading the virus around the ship are contributing to the ongoing problem.

Outbreaks on cruise ships have gained media attention, but an estimated 60 percent to 80 percent of all outbreaks of severe gastroenteritis occur on land, says the CDC. Norovirus infection is the most common cause of non-bacterial gastrointestinal illness in the United States; about 23 million cases of severe gastroenteritis a year are due to noroviruses. Noroviruses may be found in areas where people congregate together for days at a time, such as in schools, hotels, camps, nursing homes, and hospitals. Gastroenteritis is not a reportable illness in the United States except on cruise ships, so the public may be more aware of the shipboard incidences, says Forney.
By law, cruise ships that enter a U.S. port from a foreign port are required to report to the CDC, 24 hours prior to arrival, the number of passengers and crew on board who go to the ship's medical facility with gastrointestinal illness, even if the number is zero, says Forney. Having 3 percent or more of either passengers or crew reported with a gastrointestinal illness is considered an outbreak and cause for investigation.

Travelers shouldn't shun cruises, says Forney. "It is perfectly safe to go on cruise ships. The standard by which they are held for sanitation is the highest in the world." Extensive cleaning and disinfecting were carried out on ships immediately following reports of illness, Forney adds. And cruise lines continue to scrub and sanitize public areas of their ships, especially frequently touched surfaces such as handrails, elevator buttons, and even poker chips.

For More Information

- The Food and Drug Administration's Web site on foodborne illness
- The Centers for Disease Control and Prevention's (CDC) Web site on Travelers' Health
- The CDC's Vessel Sanitation Program Web site, including sanitation inspection scores for cruise ships

Surveillance Data from Swimming Pool Inspections --- Selected States and Counties, United States, May--September 2002

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http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5222a1.htm
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CDC, MMWR

Swimming is the second most popular exercise activity in the United States, with approximately 360 million annual visits to recreational water venues (*1*). This exposure increases the potential for the spread of recreational water illnesses (RWIs) (e.g., cryptosporidiosis, giardiasis, and shigellosis). Since the 1980s, the number of reported RWI outbreaks has increased steadily (*2*). Local environmental health programs inspect public and semipublic pools periodically to determine compliance with local and state health regulations. During inspections for regulatory compliance, data pertaining to pool water chemistry, filtration and recirculation systems, and management and operations are collected. This report summarizes pool inspection data from databases at six sites across the United States collected during May 1-September 1, 2002. The findings underscore the utility of these data for public-health decision making and the need for increased training and vigilance by pool operators to ensure high-quality swimming pool water for use by the public.

Data from 22,131 pool inspections were collected from the Allegheny County Department of Health, Pennsylvania (n = 713); the Florida Department of Health, Bureau of Water Programs (n = 19,604); the Los Angeles County Department of Health Services, California (n = 1,606); the St. Louis County Department of Public Health, Minnesota (n= 34); the City of St. Paul Office of License, Inspections, and Environmental Protection, St. Paul, Minnesota (n = 56); and the Wyoming Department of Agriculture (n = 118). The sites selected were a convenience sample of pool inspection programs contacted that had computerized data available. Because of data incompatibilities, some inspections conducted at some sites might not have been part of the final analysis. The data were merged into a single SAS database, including date of inspection, pool type, water-chemistry data (e.g., free chlorine and pH levels), filtration and recirculation system data (e.g., operating filters and approved water turnover rates), and policy and management data (e.g., record keeping and pool operator training). A violation was noted when an inspection item was not in compliance with state or local swimming pool codes. Other inspection items (e.g., support facilities and injury control) were not addressed in this study.

A total of 21,561 violations of pool codes were documented during the 22,131 inspections; the majority (67.5%) occurred in pools for which no pool type (e.g., hotel/motel) was specified (Table 1). Approximately one half (45.9%) of inspections indicated no violations. The majority of inspections (54.1%) found one or more violations (median: one; range: one to 12), and 8.3% of inspections resulted in immediate closure of the pool pending corrections of serious violation items (e.g., lack of disinfectant). Of total violations, water-chemistry violations comprised 38.7%, followed by filtration and recirculation system (38.6%), and policy and management (22.7%). For the 24.3% of inspections for which pool type could be ascertained (typed inspections), a range of violations occurred (Table 2). For typed inspections collecting free chlorine data, 4.5%--18.4% reported violations. The highest percentage (18.4%) of violations occurred in child wading pools, medical/therapy pools (14.3%), and hotel/motel pools (14.0%). In typed inspections, the percentage of total violations attributable to pH infractions ranged from 4.7% to 16.7%, with the highest percentage occurring in child wading pools. For child wading pools, 8% had coincident free chlorine and pH violations. Filtration and recirculation system

violations occurred in 34.0%--76.8% of typed inspections, with municipal pools having the greatest percentage. In sites where training was required, inspections demonstrated that many pool operators did not have appropriate certification (0--35.7%), with apartment/condominium complexes having the highest percentage of violations.

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Editorial Note:

The increasing number of reported pool-associated outbreaks of gastroenteritis underscores the need for proper pool maintenance as an important public health intervention (*1,2*). Approximately one fourth of these outbreaks involved chlorine-sensitive pathogens (e.g., *Escherichia coli* O157:H7 and *Shigella* spp.), which causally implicates inadequate pool maintenance and disinfection. Pool inspections are the primary means of ensuring appropriate pool operation, but resources generally allow only one to three annual inspections of each pool. As a result, pool operators are responsible for maintaining their pools with minimal public health oversight. This report documents the first attempt to analyze aggregated pool inspection data, which indicate that although some pools are well-maintained, such an infrequent inspection process cannot ensure compliance with state and local pool regulations.

Proper pool maintenance requires a combination of good water quality, functioning filtration and recirculation equipment, and well-trained staff. In this study, several violations that could facilitate the spread of RWIs were documented, with 45.9% of inspections documenting no violations. The majority of violations involved water-quality parameters (e.g., free chlorine and pH levels) or filtration and recirculation system parameters.

The interaction of pH and free chlorine levels is critical in determining the effectiveness of chlorine as a disinfectant, and effective monitoring can ensure that the optimum free chlorine and pH levels are maintained to prevent infectious disease transmission. The coincident occurrence of pH and chlorine violations indicates a substantial lack of training among pool operators, particularly those at apartment/condominium complexes. The number of overall violations highlights the need for increased vigilance in ensuring pool staff training, including information about RWI transmission, and the potential benefits of mandating training for pool operators throughout the United States. This poses a challenge for some pool types (e.g., apartment/condominium complexes and hotels/ motels) because of high staff turnover or part-time operators. Providing pool operators with more targeted education, maintenance suggestions, and forms for simple monitoring of free chlorine and pH levels might improve public health protection at these facilities.

Chlorine and pH violations were highest in wading pools, which are used by younger children, including those who wear diapers. Young children, who often swallow water indiscriminately and have an increased chance of contaminating the pool water fecally, are at increased risk for severe illness if infected. In addition, the shallow depth and relatively low volume of water in these wading pools might lead to more rapid depletion of disinfectant by ultraviolet light and higher organic contamination by the children. Wading pools require increased vigilance and testing to maintain safe disinfectant levels. Pool operators need to be aware that every time they have inadequate

disinfection in a pool, they increase the risk for spreading RWIs whenever an infected swimmer contaminates the pool.

The findings in this report are subject to at least two limitations. First, database structures for each site differed, the types of data collected and entered varied, and the data were not standardized across states or counties, thereby reducing the generalizability of the data. Second, because free chlorine levels were not entered in the database, the percentage of violations caused by low chlorine levels could not be ascertained and the range of chlorine levels recorded could not be analyzed.

Although the lack of uniform data collection among sites limited the analysis and usability of the data, this report underscores the potential usefulness of uniform collection of these data in a computerized format that can be analyzed routinely and used for full evaluation of inspection programs. CDC and its partners are developing systems-based guidance on pool operation and implementation of uniform methods for data collection and analysis. These data can then be used in the training of inspectors and operators, planning and resource allocation, and documenting trends related to particular regulatory changes and interventions.

Poor pool maintenance and operation, untrained pool staff, the potential presence of the chlorine-resistant pathogen *Cryptosporidium parvum* (*2,3*), and a swimming public that is ill-informed about the potential for spreading RWIs in the pool increase the complexity of any proposed prevention plan. Swimmer education should play a critical role in preventing the spread of RWIs. Swimmers and home pool owners should be informed that they should 1) not swim when ill with diarrhea, 2) not swallow pool water, and 3) practice good hygiene when using a pool (e.g., frequent restroom breaks, appropriate diaper changing, and hand washing). Additional information about reducing the spread of RWIs is available at http://www.healthyswimming.org.

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TABLE 1. Number and percentage of pool inspections* having specific violations of state and/or local health regulations, by type of violation and pool type — selected states and counties, United States, May–September 2002

Type of violation	Known pool type† No.	(%)	Unknown pool type§ No.	(%)	Total¶ No.	(%)
Water chemistry						
Free chlorine level	700	(13.1)	1,760	(10.5)	2,460	(11.1)
pH	502	(9.4)	1,216	(5.5)	1,718	(7.8)
Other water chemistry**	1,153	(21.4)	2,616	(15.6)	3,769	(17.0)
Filtration/Recirculation system††	2,230	(41.4)	4,374	(26.2)	6,604	(29.9)
Policy/Management						
Test kit	160	(3.0)	580	(3.5)	740	(3.4)
Pool operations training	589	(27.6)	15	(5.6)	604	(25.1)
Record keeping	669	(13.9)	2,853	(17.1)	3,522	(16.5)
Pool licensed	22	(3.8)	4	(2.9)	26	(3.6)

* Numbers reported are for those sites collecting data on the specified violation. Although 22,131 inspections were conducted, the number of inspections collecting data for each specific violation (denominator) varied widely because of a lack of uniform data collection among sites. In addition, each aggregate variable might include multiple violations and single pool inspections could have multiple violations. As a result, percentage totals do not add to 100%.

† Range of inspections collecting violation data for each pool type (R) = 573–5,385.

§ R = 140–16,746.

¶ R = 713–22,131.

** Aggregate variable. A positive could include one or more violations in any area (e.g., cyanurate levels, algae, bacterial quality, disinfectant/pH chemical feeders, total alkalinity, and calcium hardness).

†† Aggregate variable. A positive could include one or more violations in any area (e.g., backwash, cross connections, filter, flow meter, pressure gauges, recirculation system, turnover, and turbidity).

TABLE 2. Number and percentage of pool inspections* having specific violations of state and/or local health regulations, by type of violation and pool type — selected states and counties, United States, May–September 2002

Type of violation	Hotel/Motel† No.	(%)	Condominiums/ Apartments§ No.	(%)	School/ University¶ No.	(%)	Private club** No.	(%)	Wading/ Children's†† No.	(%)
Water chemistry										
–Free chlorine level	120	(14.0)	356	(12.9)	7	(8.9)	62	(13.1)	55	(13.4)
pH	91	(10.5)	252	(9.4)	4	(5.0)	29	(6.1)	69	(16.7)
Other water chemistry§§	158	(18.0)	787	(28.4)	22	(28.4)	67	(14.1)	71	(13.2)
Filtration/Recirculation system¶¶***	320	(37.1)	1,207	(43.4)	43	(49.4)	240	(51.7)	209	(39.1)
Policy/Management										
Test kit	42	(4.8)	65	(2.4)	2	(2.5)	5	(1.1)	18	(3.4)
–Pool operations training	18	(14.1)	539	(35.7)	1	(7.6)	21	(6.9)	7	(5.0)
Record keeping	65	(12.7)	464	(15.0)	4	(6.3)	48	(15.5)	61	(15.1)
–Pool licensed	0		7	(1.2)	1	(5.6)	10	(6.2)	2	(5.8)

TABLE 2. (*Continued*) Number and percentage of pool inspections* having specific violations of state and/or local health regulations, by type of violation and pool type — selected states and counties, United States, May–September 2002

Type of violation	Water parks††† No.	(%)	Medical/ Therapy§§§ No.	(%)	Municipal¶¶¶ No.	(%)	Camp grounds**** No.	(%)	Total†††† No.	(%)
Water chemistry										
Free chlorine level	15	(7.8)	2	(14.3)	5	(4.7)	5	(5.0)	706	(13.1)
pH	9	(4.7)	2	(13.3)	16	(10.5)	11	(11.1)	502	(9.4)
Other water chemistry§§	7	(3.6)	3	(47.1)	9	(8.2)	23	(22.9)	1,153	(21.4)
Filtration/Recirculation system¶¶***	72	(36.5)	9	(64.7)	82	(76.6)	35	(34.0)	2,230	(41.4)
Policy/Management										
Test kit	2		2	(12.5)	4	(3.5)	1	(3.9)	180	(3.6)
Pool operations training	2		0		0		0		589	(27.8)
Record keeping	5	(7.8)	3	(17.6)	4	(6.5)	14	(18.9)	666	(15.6)
Pool licensed	2		N/A		0		0		22	(3.8)

* Numbers reported are for those sites collecting data on the specified violation. Although a total of 5,566 inspections were conducted, the number of inspections collecting data on each specific violation (denominator) varies widely because of a lack of uniform data collection among sites. In addition, each aggregate variable might include multiple violations, and single pool inspections could have multiple violations. As a result, percentages do not add to 100%.

† Range of inspections collecting violation data for each pool type (N) = 51–875.

§ N = 155–2,987.

¶ N = 13–81.

** N = 169–478.

†† N = 68–539.

§§ N = 32–792.

¶¶ N = 9–17.

*** N = 45–1,12.

††† N = 2–103.

§§§ N = 5/2–5,385.

¶¶¶ Aggregate variable. A positive could include one or more violations in any area (e.g., eyeball water levels, slope, bacterial quality, disinfectant/pH chemical levels, total alkalinity, and calcium hardness).

**** Aggregate variable. A positive could include one or more violations in any area (e.g., backwash, cross connections filter, flowmeter, pressure gauges, recirculation system, furnace, and turbidity).

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